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Supreme Court, U.S.
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In The

Supreme Court of the United States

October Term, 1998

M3 SYSTEMS,

Cross-petitioner,

v.

C.R. BARD, INC.,

Cross-respondent.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

CONDITIONAL CROSS-PETITION FOR WRIT OF CERTIORARI

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March 29, 1999

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QUESTION PRESENTED

To sustain an antitrust claim based upon sham bad faith patent enforcement, where a patentee's chief engineer and other employees admit (i) that a competitor's product "do[es] not . . . infringe our patents" and (ii) that the infringement action against the competitor is "frivolous," is it also necessary for the antitrust plaintiff to prove by direct evidence that a representative of the patentee having specialized legal training, *i.e.*, the patentee's attorney, knew the underlying infringement action to be baseless?

PARTIES TO THE PROCEEDING

The names of all parties in the court whose judgment is sought to be reviewed appear in the caption of this cross-petition for writ of *certiorari*. Cross-petitioner is M3 Systems, Inc., which is wholly owned by Manan Medical Products, Inc., which is wholly owned by The Marmon Corporation, which is wholly owned by Marmon Holdings, Inc.

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CONDITIONAL CROSS-PETITION FOR WRIT OF CERTIORARI

If the Court grants C.R. Bard, Inc.'s petition for writ of *certiorari* to review the judgment of the United States Court of Appeals for the Federal Circuit, M3 Systems, Inc. respectfully cross-petitions for a writ of *certiorari* to review the same judgment on separate grounds.

OPINIONS BELOW

The opinion of the court of appeals is reported at 157 F.3d 1340 (Fed. Cir. 1998), and is reproduced in the appendix to the opening petition ("Opening App.") beginning at 1a. The order of the court of appeals denying Bard's petition for rehearing and declining Bard's suggestion for rehearing *in banc* is not reported, and is reproduced beginning at Opening App. 90a. A separate opinion concurring in the order of the court of appeals denying the petition for rehearing and declining the suggestion for rehearing *in banc* is not reported, and is reproduced beginning at Opening App. 92a. The judgment of the court of appeals is not reported, and is reproduced beginning at Opening App. 95a. The judgment of the district court is not reported, and is reproduced in the appendix to this cross-petition ("Cross App.") at page ca 1. The Jury's Findings on Special Interrogatories and Verdicts are reproduced beginning at Cross App. ca 2.

JURISDICTION

The jurisdiction of this Court is invoked pursuant to 28 U.S.C. § 1254(1), S. Ct. R. 10(a) and S. Ct. R. 12.5. The opinion of the United States Court of Appeals for the Federal Circuit issued on September 30, 1998. An order denying Bard's petition for rehearing and declining the suggestion for rehearing *in banc* was entered on December 7, 1998. C.R. Bard, Inc.'s petition for writ of *certiorari* was docketed on February 26, 1999.

STATUTORY PROVISIONS INVOLVED

The statutory provisions involved in this Cross-Petition are 15 U.S.C. §§ 2 and 15(a).

15 U.S.C. § 2 provides in pertinent part:

> Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $10,000,000 if a corporation, or, if any other person, $350,0000, or by imprisonment not exceeding three years, or by both said punishments, in the discretion of the court.

15 U.S.C. § 15(a) provides in pertinent part:

> Except as provided in subsection (b) of this section, any person who shall be injured in his business or property by reason of anything forbidden in the antitrust laws may

> sue therefor in any district court of the United States in the district in which the defendant resides or is found or has an agent, without respect to the amount in controversy, and shall recover threefold the damages by him sustained, and the cost of suit, including a reasonable attorney's fee. . . .

STATEMENT OF THE CASE

A. The Pertinent Events Leading Up to the Underlying Infringement Suit

In 1987, C.R. Bard, Inc. ("Bard") acquired distribution rights to an automated biopsy system comprising a reusable two-stage, spring-loaded biopsy "gun" and replacement needles to be used in the gun. (J14060-96.)[1] In 1989, Bard purchased the remaining rights and assets relating to this particular biopsy system. (J12839-921; J12922-930; J7076-80.) A biopsy gun works by propelling a notched inner needle into a mass, then propelling an outer cannula over the inner needle, thereby trapping tissue in the notched end of the inner needle for later retrieval and examination.

Among the assets that Bard purchased was U.S. Patent No. 4,699,154 (the " '154 patent"), which covered certain elements of its automated gun but did not cover the

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[1] The "J" citations are to the joint appendix on appeal; the "a" citations are to the appendix to the opening petition for writ of *certiorari;* and the "c" citations are to the appendix to this cross-petition.

replacement needles. (J11599-606.) During the late 1980's, other companies, including M3 Systems, Inc. ("M3"), manufactured and sold replacement needles for use in biopsy guns. As Bard soon learned, the money was in the needles, not the guns. The guns lasted for years. Each needle could be used only once. Therefore, every automated needle biopsy required the purchase of a replacement needle. To address the needle competition it faced, Bard requested the Patent and Trademark Office ("PTO") to reissue and expand the scope of the '154 patent to cover not only features of the gun, but certain features of the replacement needle, as well. (J13754-904.) In applying for the reissue patent, Bard claimed that its needle claims had been inadvertently overlooked in the original '154 application. (*Id.*; *see also* Bard's Opening Brief on Appeal at 14.)

After several years of consideration, negotiation, and limitation, the PTO reissued the patent as U.S. Patent No. RE34,056 (the " '056 patent"), which covered features of the gun and a very narrow feature of the needle. (J13589-597; J13754-904.) Specifically, each of the needle claims in the '056 patent require a flange on the rear hub of the needle assembly for coupling with the rear propelling drive of the gun. (J13589-597, claims 9-12, 21-23.) In all other respects, the needle elements of the '056 patent were identical to the prior art manual needles and would not – without the claimed flange – be newly patentable. (J13754-904.)

After the '056 patent issued, M3 designed around the newly-claimed flange feature by re-engineering the rear hub of its needle to remove the flange. (J11641; J9184;

J14955-57; J8445-47.) Notwithstanding that M3's re-engineered needle did not have a flange as required by the '056 patent, Bard sued M3, claiming that the flangeless needle infringed the '056 patent. The jury found that M3's flangeless needle did not infringe and that Bard had no basis to assert that it did. (ca 13-16; ca 22-26; J10122-3.)[2]

B. The Evidence Showed, and the Jury and the Trial Court Found, That Bard Sued M3 for Patent Infringement in Bad Faith, Without A Reasonable Belief That The Case Could Be Won

M3 established by "clear and convincing" evidence that Bard's claim of infringement was "objectively baseless" and brought in "bad faith," and the jury so found. (ca 22-26; J10122-3.) Specifically, Mr. Ken Eakin testified that while employed as Bard's biopsy product manager he was repeatedly told by Bard engineers – including Rich Griffith, Bard's chief engineer – that M3's flangeless needle did not infringe the '056 patent. (J8876-78.) Indeed, Griffith repeatedly told Eakin that Bard's "patent claims" against M3 "were frivolous." (J8878; J8897.)[3]

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[2] Because it affirmed the jury's verdict that the '056 patent was invalid, the Federal Circuit had no occasion to consider the jury's verdicts of non-infringement.

[3] There can be no question that Griffith was competent to make evidentiary admissions on behalf of Bard. Griffith was Bard's chief engineer and a member of Bard's biopsy management team; Bard produced Griffith as its Fed. R. Civ. P. 30(b)(6) witness on infringement issues; and, according to the testimony at trial, Griffith was familiar with the '056 patent and the accused products. (J8868-8902; J14820-23.)

An internal Bard memo dated March 1, 1994 (after Bard sued M3 for infringement), contained a similar admission:

> several . . . manufacturers [including M3] have withdrawn their old hub needles and have replaced them with new hubs *that do not, in the opinion of the engineering group, infringe our patents.*

(ca 35 (emphasis added); *see also* J8877.) Before this memo was finalized, it was circulated to "everyone in Bard Radiology" including the division head, and no one said it was in any way inaccurate. (J8878-79.) Bard did not call Griffith (or anyone else) to the stand either to rebut this evidence or to explain the basis for Bard's repeated admissions that M3's flangeless needle did not infringe the '056 patent. This unrebutted evidence stands as an unequivocal admission by Bard that it knew that M3 was not guilty of infringement.

Yet, Bard sued anyway, claiming that M3's flangeless needles infringed the '056 patent. And, the jury learned why. Bard's biopsy division head told Eakin that M3 was not a "large enough" company "to carry on [the lawsuit] long term" and that the case would be "settled out of court" or "not pursued." (J8884.) The jury also learned that Bard had tried to conceal its admission, first by improperly withholding the "non-infringement" memo from discovery and, then, by redacting the key admission from it. (ca 28-47, at ca 35.)

This was not M3's only proof that Bard lacked a good faith basis to sue. The evidence also showed that Bard had not received a legal opinion that M3's flangeless

needle infringed the '056 patent. (J14820-23.) Yet, Bard sued M3 anyway.

The jury also learned that Bard had tried to conceal the fact that it had not obtained a legal opinion of infringement. Specifically, Bard was shown to have "doctored" the minutes of a biopsy managers meeting by secretly redacting sentences showing that Bard knew it did not have a legal basis to sue M3 for infringing the '056 patent. (J14820-23.) The jury also learned that Bard tried to cover up this evidence tampering. The Bard executive who had taken the minutes of the meeting lied at his deposition by denying that anything had been deleted from the minutes. (J7426-33.)

The evidence concerning Bard's failure to obtain a legal opinion of infringement went unrebutted. Bard certainly never produced any such legal opinion, and Bard's false deposition testimony effectively cut off inquiry into the subject. Indeed, Bard withheld more than eight hundred documents from discovery based upon the attorney-client and attorney work product privileges. (J7343.)

In sum, M3 put in several days of *unrebutted* testimony (by Bard employees, former Bard employees, an expert skilled in the art, and the inventors themselves) that established to the jury's satisfaction not only that M3's flangeless replacement needles did not infringe Bard's patents, but that Bard knew that M3 did not infringe, knew that it did not have a legal basis to sue, and believed M3 was too small a company to defend against the admittedly "frivolous" patent litigation action.

C. The Evidence Showed, and the Jury and the Trial Court Found, That Bard Had Monopolized The Relevant Market for Replacement Biopsy Needles

M3 also proved that Bard possessed monopoly power in the relevant market for biopsy needles and pursued the sham patent infringement action against M3 to maintain and further that monopoly. First, M3 proved the existence of a relevant market for replacement needles and Bard's monopoly power therein through (i) economic, industry and medical witnesses and (ii) extensive market data. (J8964-9125; J15326-43.) Second, M3 proved that Bard had a 71% share of the market for reusable needles. (ca 55.) Third, M3 proved that Bard sought to drive M3 (and other makers of flangeless needles) from the market with its bogus patent claims and, in doing so, hoped to further increase its already-dominant market share to 90%. (ca 56.) Among the reams of evidence presented on this issue was Bard's 1994-1996 Three Year Plan, which set forth Bard's intent to "[i]ncrease market share through patent infringement action. . . . " as the top item on the list of Bard Radiology's "Key Divisional Strategies." (ca 57; *see also* J14684-719, J14720-60; J14831-43, J14866-73.) Another Bard executive confirmed that Bard's "strategy was to take back the sales being made by these low-priced needle sellers and get it back by claiming that they were infringing [Bard's] patents. . . . " (J8334-35.)

Based upon the above evidence, after a four-week trial, the jury found Bard liable for monopolizing the relevant market for replacement biopsy needles in violation of Section 2 of the Sherman Act. The trial judge, who

received the above evidence and more, denied Bard's motion for judgment as a matter of law and entered judgment for M3 and against Bard. (ca 1.)

D. The Federal Circuit Reversed the Sham Litigation Verdict Because Bard's Admissions that its Patent Claims Were "Frivolous" Did Not Come From Its Patent Attorneys or Other Persons Proven to Be Knowledgeable About the Doctrine of Equivalents

Despite the above evidence, including Bard's outright admissions that M3's flangeless needle did not infringe the '056 patent, the Federal Circuit reversed the jury's sham litigation verdict. It did so based upon an unprecedented legal rationale. Specifically, the Federal Circuit reversed because there was no direct evidence that the Bard representatives who had admitted that the infringement claim against M3 was baseless and "frivolous" were "familiar with the doctrine equivalents." (Opening App. at 55a.)[4]

The doctrine of equivalents is a rule of patent law that holds that an accused product may infringe, even though it does not literally read upon the patent claims, if the differences between the claimed product and the accused product are insubstantial. *Graver Tank & Manufacturing Co. v. Linde Air Products, Co.*, 339 U.S. 605, 610, 70 S. Ct. 854, 857 (1950); *see also Hilton Davis Chemical Co. v. Warner-Jenkinson Co.*, 62 F.3d 1512, 1519 (Fed. Cir. 1995)

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[4] Bard did not make this argument to the trial court or in its opening brief on appeal and, thus, M3 never had opportunity to address it prior to the Federal Circuit's holding below.

(discussing the various considerations to be taken into account in determining whether a product infringes a patent by virtue of the doctrine of equivalents).

In holding that Bard's unqualified admissions of non-infringement were insufficient as a matter of law to sustain an antitrust verdict, the Federal Circuit has created a rule that an antitrust claim based upon bad faith patent enforcement can be proved only by direct evidence that a representative of the patentee having specialized legal training, presumably the patentee's attorney, knew that the underlying infringement claim was baseless. Such a showing can be made only by (i) an admission of counsel, or (ii) an admission from a company representative who is shown to have been thoroughly advised by counsel as to the proper application of the *Graver Tank* and *Hilton Davis* factors (or other pertinent patent doctrines). This, of course, would require a waiver of the attorney-client privilege.

This newly-announced standard of proof is in direct conflict with *Handgards, Inc. v. Ethicon, Inc.*, 743 F.2d 1282, 1289 (9th Cir. 1984) (*"Handgards II"*), *cert. denied*, 469 U.S. 1190 (1985), and, as a practical matter, would make it impossible to prove a sham litigation claim.

REASONS FOR GRANTING THE WRIT

I. The Federal Circuit Has Entered A Decision In Conflict With the Ninth Circuit's Opinion in *Handgards v. Ethicon* on the Same Important Matter of Whether An Antitrust Claim For Bad Faith Patent Enforcement Can Be Sustained Without Direct Evidence That The Patentee's Attorney Knew The Case Was Objectively Baseless

As explained above, in reversing the sham litigation verdict, the Federal Circuit has created a new rule that an antitrust claim for bad faith, sham patent enforcement can be sustained only by direct evidence that a representative of the patentee having specialized legal training, *i.e.*, the patentee's attorney, knew the claim to be baseless. This holding is in direct conflict with the Ninth Circuit's opinion in *Handgards II*.[5] In *Handgards II* – analogous to the instant case – a former employee of Ethicon testified that another employee had told him that the patent upon which Ethicon sued was invalid. Just as the Federal Circuit concluded below, Ethicon argued that the relevant inquiry was whether Ethicon's attorney knew the patent to be invalid. *Id.* at 1290. The Ninth Circuit rejected that argument:

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[5] The Ninth Circuit's earlier decision in the same case is the seminal opinion establishing antitrust liability for bad faith patent enforcement conduct when the patentee is shown to have exclusionary power in a relevant antitrust market. *Handgards, Inc. v. Ethicon, Inc.*, 601 F.2d 986, 992-96 (1979) ("*Handgards I*"), *cert. denied*, 469 U.S. 1190 (1985). *See also Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 877 (Fed. Cir. 1985) (holding that the *Handgards* standard applies to patent suits brought with knowledge that patents are not infringed).

> [E]vidence that the inventor/patentee/ employee knew the patent was invalid is very probative of Ethicon's knowledge. We refuse to establish a requirement that Handgards had to prove that the patent attorney knew the Gerard patent was invalid. *(citations omitted)*

743 F.2d at 1290. There is no way to reconcile the Federal Circuit's opinion below with *Handgards II*, and the Ninth Circuit has it right.

In *Handgards I*, the Ninth Circuit noted the inherent clash between the policies of patent and antitrust law. 601 F.2d 986. While patentees should be permitted to test the validity of their patents in court, "infringement actions initiated and conducted in bad faith contribute nothing to the furtherance of the policies of either the patent law or the antitrust law." *Id.* at 993. The Ninth Circuit also provided a solution to this dichotomy. A jury hearing a bad faith enforcement claim must be "instructed that a patentee's infringement suit is presumptively in good faith and that this presumption can be rebutted by clear and convincing evidence." *Id.* The jury below was so instructed and, based upon the evidence described above, found that M3 had sufficiently rebutted the presumption. (J10122-3; ca 22-26.)

In *Handgards II*, as in the current case, there was no evidence that the person making the admission had received instruction in the finer points of patent law or was otherwise knowledgeable about how to legally determine whether a particular piece of prior art is invalidating. Nonetheless, the Ninth Circuit found his admission that the patent was "invalid" to be "very probative" as to Ethicon's knowledge – and sufficient to overcome the

presumption of good faith. *Id.* The evidence in *Handgards II*, while clear and convincing, did not approach the overwhelming and unrebutted proof of bad faith patent enforcement that the Federal Circuit has held insufficient as a matter of law to sustain a jury verdict. (*See, supra, Statement of Case* § B.)

Thus, in *Handgards II*, the Ninth Circuit ruled on the nature and quality of the evidence that is required to overcome the presumption of good faith and expressly refused to establish a requirement that the antitrust plaintiff prove that the patentee's attorney knew the infringement claim to be baseless. 743 F.2d at 1290.[6] As explained

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[6] The evidentiary standard set forth in *Handgard II* is consistent with this Court's decision in *Professional Real Estate Investors v. Columbia Pictures*, 508 U.S. 49, 113 S. Ct. 1920 (1993) ("*PRE*"), and the Federal Circuit's holding below is not. In *PRE*, the Court outlined a two-part definition of sham litigation: (i) the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits, and (ii) the lawsuit must be subjectively baseless in the sense that the litigant seeks to use the litigation "process" as an "anticompetitive weapon." *Id.*, 508 U.S. at 60-61, 113 S. Ct. at 1928. (The jury below was instructed consistent with *PRE* (J10122-3).) The Court did not address the nature and character of the evidence required to prove either the objective or subjective component of a sham litigation claim. However, the Court drew a parallel between sham litigation and common law malicious prosecution and likened the objectively baseless test to a probable cause determination. *Id.*, 508 U.S. at 60-61, 113 S. Ct. at 1928. The similarities between sham litigation and malicious prosecution – as well as common sense – instruct that to the extent the advice an antitrust defendant received from counsel has any bearing on a sham litigation claim, it must be in the nature of an affirmative defense on which the *antitrust defendant* bears the burden of proof or, at least, the burden of

infra, Reasons for Granting the Writ § II, this makes perfect sense because advice of counsel is a defense to a claim for sham litigation, not an additional element of the claim that an antitrust plaintiff is somehow required to initially disprove. Once the antitrust plaintiff presents evidence sufficient to overcome the presumption of good faith, it is up to the patentee to come forward with affirmative proof that it pursued the patent claim based upon the advice of counsel – not the other way around.

In sum, the Federal Circuit's holding below undermines both *Handgards I* and *Handgards II*, which together have long provided the standards by which bad faith patent enforcement actions are determined.

II. The Federal Circuit Has Entered a Decision that Effectively Shifts the Burden to the Antitrust Plaintiff to Disprove the Existence of an Affirmative Defense and Makes It Impossible as a Practical Matter to Prove Bad Faith Patent Enforcement

A plaintiff alleging bad faith litigation or malicious prosecution does not bear the burden of proving that the defendant's attorney knew the claim to be frivolous. Rather, the defendant's reliance on advice of counsel in bringing the claim is an affirmative defense to malicious prosecution, which it is the defendant's burden to plead and prove. *See Smith v. St. Paul Fire & Marine Ins. Co.*, 905 F. Supp. 909, 920 (D. Kan. 1995) ("Reliance on counsel is

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coming forward with evidence. Proof that counsel advised a litigant that his claim was baseless cannot realistically be made part of the antitrust claimant's *prima facie* case. *See* Discussion *infra, Reasons for Granting the Writ* § II.

in the nature of an affirmative defense which serves to rebut the allegation of probable cause [an element of malicious prosecution]."), *aff'd*, 99 F.3d 1150 (10th Cir. 1996); *Salmen v. Kamberos*, 565 N.E.2d 6, 11 (Ill. App. Ct. 1990) ("Reliance on the advice of an attorney is a defense to a claim of malicious prosecution."). Indeed, the advice-of-counsel defense requires the defendant to demonstrate that (1) the advice was obtained and followed in good faith (and not as a pretext or cover), (2) defendant made a full and fair disclosure to counsel, and (3) counsel was disinterested in the claim. *Alexander v. Alexander*, 229 F.2d 111, 117 (4th Cir. 1956); *Salmen*, 565 N.E.2d at 11 ("[D]isclosure of all the facts and circumstances is necessary to establish the defense of advice-of-counsel . . . .").

The Federal Circuit's holding – that a bad faith enforcement claim is insufficient absent proof that a representative of the patentee having specialized legal training, *i.e.*, the patentee's attorney, knew the patent claim to be baseless – turns the advice-of-counsel defense on its head. This newly-announced standard of proof effectively shifts to the antitrust plaintiff the burden of showing that the patentee's counsel *knew that the infringement action was baseless and advised against its filing*. If the patentee does not waive the attorney-client privilege, there is virtually no way that the antitrust plaintiff could ever meet this burden.

Bard did not assert an advice-of-counsel defense to M3's antitrust claim. Nor did Bard present any evidence that its infringement claim against M3 was based upon any advice of counsel. Just the opposite, the evidence showed that Bard charged M3 with infringement without an opinion from counsel, and Bard did not rebut this

evidence. (*See, supra, Statement of the Case* § B.) Bard also remained silent in the face of several internal Bard admissions that the infringement action was frivolous and filed with the belief that tiny M3 would exit the market without a fight. (*Id.*) Still further, Bard withheld more than eight hundred documents from discovery purportedly based upon the attorney-client and attorney work product privileges, and Bard resisted every attempt by M3 to obtain documents from the privilege log. (*Id.*)

Indeed, Bard's claim of privilege precluded it from raising the very defense that the Federal Circuit held was M3's burden to disprove. This is because a party asserting an advice-of-counsel defense must waive the attorney-client privilege. *Glenmede Trust Co. v. Thompson*, 56 F.3d 476, 486 (3d Cir. 1995) ("Under such circumstances, the client has made a conscious decision to inject the advice of counsel as an issue in the litigation."); *Solomon v. Kimberly-Clark Corp.*, No. 98 C 7598, 1999 WL 89570, at *2 (N.D. Ill. Feb. 12, 1999) (finding that a patent-infringement defendant asserting an advice-of-counsel defense had thereby waived both the attorney-client and work product privileges). This waiver encompasses not only the otherwise-privileged materials necessary to support such defense, but broadly covers all communications that would allow the opposing party to test what information passed between client and counsel relating to that advice. *Id.* (finding that broad waiver is necessary to prevent a party from unfairly dictating the scope of discovery). As discussed above, Bard never made any waiver of the attorney-client privilege during discovery or at trial, much less the sort of sweeping waiver that would be consistent with an advice-of-counsel defense. Thus, M3

had no way of showing what, if anything, Bard's attorney advised it with respect to the "doctrine of equivalents."

If the Federal Circuit's opinion below is allowed to stand, a patent plaintiff can avoid all possibility of antitrust liability for bad faith patent enforcement by either declining to obtain an opinion of counsel or asserting the attorney-client privilege. Such a result is contrary to *Handgards I*, *Handgards II*, and this Court's opinion in *PRE*.

CONCLUSION

If the Court grants C.R. Bard, Inc.'s petition for writ of *certiorari* to review the judgment of the United States Court of Appeals for the Federal Circuit, this cross-petition for writ of *certiorari* should also be granted.

Respectfully submitted,

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March 29, 1999

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

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Case Number: 1:93-cv-04788

Title: C R Bard Inc v. M3 Syst Inc

Assigned Judge: Honorable Elaine E. Bucklo

MINUTE ORDER of 12/18/95 by Hon. Elaine E. Bucklo: Plaintiff's motion for a judgment as a matter of law for a finding that M3 Systems, Inc. has not proven that it is entitled to intervening rights [295-1] or in the alternative, a new trial is denied. Judgment is entered in favor of defendant and against plaintiff in the amount of $4,500,000.00 (trebling the jury verdict of $1,500,000.00, as required). Any pending motion in this case is terminated as moot. Mailed notice

This docket entry was made by the Clerk on December 20, 1995

ATTENTION: This notice is being sent pursuant to Rule 77(d) of the Federal Rules of Civil Procedure or Rule 49(c) of the Federal Rules of Criminal Procedure. It was generated by ICMS, the automated docketing system used to maintain the civil and criminal dockets of this District. If a minute

order or other document is enclosed, please refer to it for additional information.

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

C.R. BARD, INC., Plaintiff-Counterdefendant, v. M3 SYSTEMS, INC., Defendant-Counterclaimants.	Civil Action No. 93-C-4788 Judge Elaine E. Bucklo Magistrate Judge Lefkow (Filed Sept. 28, 1995)

SPECIAL INTERROGATORIES AND VERDICTS

We, the jury, for our special findings, determinations and verdicts, hereby respond as follows. NOTE: All questions are to be answered unless otherwise indicated.

QUESTIONS CONCERNING WHETHER OR NOT C.R. BARD'S U.S. PATENT NO. RE 34,056 IS INVALID

1. Do you find, by clear and convincing evidence, that the subject matter of the following claims of the '056 patent, as interpreted by the Court, were fully anticipated by a single prior art reference?

   a. With respect to Claim 9

      ANSWER: Yes ✓ or No ___

   b. With respect to Claim 10

      ANSWER: Yes ✓ or No ___

c. With respect to Claim 11

ANSWER: Yes ✓ or No ___

d. With respect to Claim 12

ANSWER: Yes ✓ or No ___

e. With respect to Claim 21

ANSWER: Yes ✓ or No ___

f. With respect to Claim 22

ANSWER: Yes ✓ or No ___

g. With respect to Claim 23

ANSWER: Yes ✓ or No ___

2. Do you find, by clear and convincing evidence, that the asserted claims of the '056 patent, as interpreted by the Court, are invalid because the failure to obtain the asserted '056 claims in the '154 patent was not an error which could be corrected by reissue?

ANSWER: Yes ✓ or No ___

3. Do you find, by clear and convincing evidence, that the following claims of the '056 patent, as interpreted by the Court, are invalid because the named inventors did not themselves invent the claimed subject matter?

a. With respect to Claim 9

ANSWER: Yes ✓ or No ___

b. With respect to Claim 10

ANSWER: Yes ✓ or No ___

c. With respect to Claim 11

ANSWER: Yes ✓ or No ___

d. With respect to Claim 12

ANSWER: Yes ✓ or No ___

e. With respect to Claim 21

ANSWER: Yes ✓ or No ___

f. With respect to Claim 22

ANSWER: Yes ✓ or No ___

g. With respect to Claim 23

ANSWER: Yes ✓ or No ___

4. Do you find, by clear and convincing evidence, that the following claims of the '056 patent, as interpreted by the Court, are invalid because the claimed invention (the "second generation device") was patented or described in a printed publication in this or a foreign country or in public use or on sale in the United States more than one year prior to the actual date of the filing of the application for the '154 patent, i.e., more than one year before July 30, 1986?

a. With respect to Claim 9

ANSWER: Yes ✓ or No ___

b. With respect to Claim 10

ANSWER: Yes ✓ or No ___

c. With respect to Claim 11

ANSWER: Yes ✓ or No ___

d. With respect to Claim 12

ANSWER: Yes ✓ or No ___

e. With respect to Claim 21

ANSWER: Yes ✓ or No ___

f. With respect to Claim 22

ANSWER: Yes ✓ or No ___

g. With respect to Claim 23

ANSWER: Yes ✓ or No ___

5. Do you find, by clear and convincing evidence, that the subject matter of the following claims of the '056 patent, taken as a whole, as interpreted by the Court, would have been obvious to a person of ordinary skill in the art at the time of the invention, considering any objective evidence of non-obviousness?

a. With respect to Claim 9

ANSWER: Yes ✓ or No ___

b. With respect to Claim 10

ANSWER: Yes ✓ or No ___

c. With respect to Claim 11

ANSWER: Yes ✓ or No ___

d. With respect to Claim 12

ANSWER: Yes ✓ or No ___

e. With respect to Claim 21

ANSWER: Yes ✓ or No ___

f. With respect to Claim 22

ANSWER: Yes ✓ or No ___

g. With respect to Claim 23

ANSWER: Yes ✓ or No ___

6. Do you find by clear and convincing evidence that BARD misused the '056 patent?

ANSWER: Yes ✓ or No ___

QUESTIONS CONCERNING WHETHER OR NOT C.R. BARD COMMITTED FRAUD BEFORE THE PATENT OFFICE WITH RESPECT TO THE '056 PATENT

7. Do you find by clear and convincing evidence that Bard committed fraud before the United States Patent and Trademark Office relative to the asserted claims of the '056 patent?

ANSWER: Yes ✓ or No ___

QUESTIONS CONCERNING WHETHER OR NOT C.R. BARD'S U.S. PATENT NO. 4,944,308 IS INVALID AND/OR UNENFORCEABLE

8. Do you find, by clear and convincing evidence, that the subject matter of the following claims of BARD's '308 patent, as interpreted by the Court, were fully anticipated by a single prior art reference?

a. With respect to Claim 15

ANSWER: Yes ✓ or No ___

b. With respect to Claim 16

ANSWER: Yes ✓ or No ___

9. Do you find, by clear and convincing evidence, that the subject matter of the following claims of the '308 patent, taken as a whole, as interpreted by the court, would have been obvious to a person of ordinary skill in the art at the time of the invention, considering any objective evidence of non-obviousness?

a. With respect to Claim 15

ANSWER: Yes ✓ or No ___

b. With respect to Claim 16

ANSWER: Yes ✓ or No ___

10. Do you find, by clear and convincing evidence, that the following claims of the '308 patent, as interpreted by the Court, are invalid on the basis that they are not supported by the description contained in the specification?

a. With respect to Claim 15

ANSWER: Yes ✓ or No ___

b. With respect to Claim 16

ANSWER: Yes ✓ or No ___

11. Do you find clear and convincing evidence in that BARD misused the '308 patent?

ANSWER: Yes ✓ or No ___

QUESTIONS CONCERNING WHETHER OR NOT C.R. BARD COMMITTED FRAUD BEFORE THE PATENT OFFICE WITH RESPECT TO THE '308 PATENT

12. Do you find by clear and convincing evidence that Bard committed fraud before the United States Patent and Trademark Office with respect to the asserted claims of the '308 patent?

ANSWER: Yes ✓ or No ___

QUESTIONS CONCERNING WHETHER OR NOT M3 SYSTEMS HAS INFRINGED C.R. BARD'S '056 PATENT WITH RESPECT TO M3 SYSTEMS' ORIGINAL ACN AND SACN NEEDLES

13. Do you find, by a preponderance of the evidence, that M3 SYSTEMS' original ACN and SACN needles directly infringe the following claims of the '056 patent?

Claim 9. [A biopsy needle for use with a tissue sampling device having a housing, a first slide mounted for longitudinal motion within said housing, and a second slide having a transverse recess formed therein and being mounted for longitudinal motion within said housing, said biopsy needle comprising:

a hollow first needle having proximal and distal ends;

a second needle extending through said hollow first needle and freely slidable therewithin, said second needle having proximal and distal ends;

a first head mounted to said proximal end of said first needle, said first head having front and rear flanges

formed thereon in spaced-apart relation for receiving said first slide therebetween, such that when said first head is placed on said first slide, said slide is mateingly received between said front and rear flanges to couple said first needle to said first slide; and

a second head mounted to said proximal end of said second needle, said second head having a flange thereon dimensioned to be received within said transverse recess of said second slide such that when said second head is placed on said second slide, said flange on said second head engages said transverse recess in said second slide to couple said second needle to said second slide.]

Claim 9 Yes _ or No ✓

(Infringes) (Does Not Infringe)

Claim 10. [The biopsy needle of Claim 9, wherein said second slide further includes a guide pin projecting across said transverse recess, and wherein said flange on said second head further comprise a slit dimensioned to receive said guide pin therewithin such that when said flange on said second head engages said transverse recess in said second slide, said guide pin is received within said slit to prevent rotational movement of said second needle with respect to said second slide.]

Claim 10. Yes_ or No ✓

(Infringes) (Does Not Infringe)

Claim 11. [The biopsy needle of Claim 9, wherein said second needle further comprises a tissue sampling recess formed adjacent said distal end thereof.]

Claim 11 Yes_ or No ✓

(Infringes) (Does Not Infringe)

Claim 12. [A biopsy needle for use with a tissue sampling device having a housing, a first slide mounted for longitudinal motion within said housing, and a second slide having a transverse recess formed therein with a guide pin projecting across said transverse recess, said second slide being mounted for longitudinal motion within said housing, said biopsy needle comprising

a hollow outer needle having proximal and distal ends;

an inner needle extending through said hollow outer needle and freely slidable therewithin, said inner needle having a proximal end, a pointed distal end, and a tissue sampling recess formed adjacent said distal end;

a first head mounted to said proximal end of said outer needle, said first head having front and rear flanges formed thereon in spaced-apart relation for receiving said first slide therebetween such that when said first head is placed on said first slide, said slide is mateingly received between said front and rear flanges to couple said outer needle to said first slide; and

a second head mounted to said proximal end of said inner needle, said second head having a flange thereon dimensioned to be received within said transverse recess of said second slide, said flange defining a slit dimensioned to receive said guide pin therein such that when said second head is placed on said second slide, said flange on said second head engages said transverse recess in said second slide and said guide pin is received within said slit to couple said inner needle to said second slide and to prevent rotational movement of said inner needle.]

Claim 12 Yes_ or No ✓

(Infringes) (Does Not Infringe)

Claim 21. [A biopsy needle for use with a tissue sampling device having a housing with a forward end, a first slide mounted for longitudinal motion within said housing, and a second slide mounted for longitudinal motion within said housing, said biopsy needle comprising:

a hollow first needle having proximal and distal ends;

a second needle extending through said hollow first needle and freely slidable therewithin, said second needle having proximal and distal ends;

a first head mounted to said proximal end of said hollow first needle, said first head including first flange means associated therewith for coupling said hollow first needle to said first slide for longitudinal motion both toward and away from said forward end of said housing; and

a second head mounted to said proximal end of said second needle, said second head including second flange means associated therewith for coupling said second needle to said second slide for longitudinal motion both toward and away from said forward end of said housing.]

Claim 21 Yes_ or No ✓

(Infringes) (Does Not Infringe)

Claim 22. [The biopsy needle of Claim 21, wherein said first flange means associated with said first head

comprises front and rear flanges formed on said first head in spaced-apart relation for receiving said first slide therebetween so as to couple said hollow first needle to said first slide for longitudinal motion both toward and away from said forward end of said housing.]

Claim 22 Yes_ or No ✓

(Infringes) (Does Not Infringe)

Claim 23. [The biopsy needle of Claim 21, wherein said second flange means associated with said second head comprises a flange formed on said second head and dimensioned to be received within a transverse recess formed in said second slide so as to couple said second needle to said second slide for longitudinal motion both toward and away from said forward end of said housing.]

Claim 23 Yes_ or No ✓

(Infringes) (Does Not Infringe)

QUESTIONS CONCERNING WHETHER OR NOT M3 SYSTEMS HAS INFRINGED C.R. BARD'S '056 PATENT WITH RESPECT TO THE CURRENT ACN OR SACN NEEDLES

14. Do you find, by a preponderance of the evidence that M3 SYSTEMS' accused current ACN or SACN needles directly infringe the following claims of the '056 patent?

Claim 9. [A biopsy needle for use with a tissue sampling device having a housing, a first slide mounted for longitudinal motion within said housing, and a second slide having a transverse recess formed therein and

being mounted for longitudinal motion within said housing, said biopsy needle comprising:

a hollow first needle having proximal and distal ends;

a second needle extending through said hollow first needle and freely slidable therewithin, said second needle having proximal and distal ends;

a first head mounted to said proximal end of said first needle, said first head having front and rear flanges formed thereon in spaced-apart relation for receiving said first slide therebetween, such that when said first head is placed on said first slide, said slide is mateingly received between said front and rear flanges to couple said first needle to said first slide; and

a second head mounted to said proximal end of said second needle, said second head having a flange thereon dimensioned to be received within said transverse recess of said second slide such that when said second head is placed on said second slide, said flange on said second head engages said transverse recess in said second slide to couple said second needle to said second slide.]

Claim 9 Yes_ or No ✓

(Infringes) (Does Not Infringe)

Claim 11. [The biopsy needle of Claim 9, wherein said second needle further comprises a tissue sampling recess formed adjacent said distal end thereof.]

Claim 11 Yes_ or No ✓

(Infringes) (Does Not Infringe)

Claim 21. [A biopsy needle for use with a tissue sampling device having a housing with a forward end, a first slide mounted for longitudinal motion within said housing, and a second slide mounted for longitudinal motion within said housing, said biopsy needle comprising:

a hollow first needle having proximal and distal ends;

a second needle extending through said hollow first needle and freely slidable therewithin, said second needle having proximal and distal ends;

a first head mounted to said proximal end of said hollow first needle, said first head including first flange means associated therewith for coupling said hollow first needle to said first slide for longitudinal motion both toward and away from said forward end of said housing; and

a second head mounted to said proximal end of said second needle, said second head including second flange means associated therewith for coupling said second needle to said second slide for longitudinal motion both toward and away from said forward end of said housing.]

Claim 21 Yes_ or No ✓

(Infringes) (Does Not Infringe)

Claim 22. [The biopsy needle of Claim 21, wherein said first flange means associated with said first head comprises front and rear flanges formed on said first head in spaced-apart relation for receiving said first slide therebetween so as to couple said hollow first needle to

said first slide for longitudinal motion both toward and away from said forward end of said housing.]

Claim 22 Yes_ or No ✓

(Infringes) (Does Not Infringe)

QUESTION CONCERNING WHETHER OR NOT M3 SYSTEMS HAS WILLFULLY INFRINGED C.R. BARD'S '056 PATENT

Answer Question No. 15 as to only those claims of the '056 patent you found infringed in response to Question Nos. 13 and/or 14 above, if any:

15. If you found, in response to Question Nos. 13 and/or 14 that any of claims 9-12 and/or 21-23 were infringed by M3 SYSTEMS' accused original ACN or SACN needles and/or claims 9, 11, 21 and/or 22 were infringed by M3 SYSTEMS' accused current ACN or SACN needles, do you find by clear and convincing evidence, that M3 SYSTEMS' infringement of same was willful?

ANSWER: Yes___ or No___

QUESTIONS CONCERNING WHETHER OR NOT M3 SYSTEMS HAS INFRINGED C.R. BARD'S '308 PATENT

16. Do you find, by a preponderance of the evidence, that M3 SYSTEMS' accused products directly infringe any of the following claims of the '308 patent?

Claim 15. [A tissue sampling device comprising]

a guide sleeve having front and rear guide sleeve ends and defining a longitudinal axis extending between said front and rear guide sleeve ends, said front guide sleeve end having an opening therethrough;

a hollow first needle positioned within said guide sleeve and extendible from said opening, said hollow first needle being movable along said axis;

a second needle extending through said hollow first needle and movable along said axis, said second needle having a tip which is extendible from said hollow first needle and said opening, and said second needle further including a tissue sample receiving recess;

a first needle head coupled to said hollow first needle and mounted within said guide sleeve for movement along said axis to move said hollow first needle along said axis;

a second needle head coupled to said second needle and mounted within said guide sleeve for movement along said axis to move said second needle along said axis;

a first spring disposed within said guide sleeve and operatively associated with said second needle head, said first spring being capable of being placed into an energized mode to store energy, and said first spring being releasable from said energized mode to propel said second needle head along said axis toward said opening, such that said tip of said second needle is extended from said hollow first needle, whereby a tissue sample can be captured within said recess;

a second spring positioned within said guide sleeve and operatively associated with said first needle head, said second spring being capable of being placed into an energized mode to store energy, and said second spring being releasable from said energized mode to propel said first needle head along said axis towards said opening, said hollow first needle being extended from said opening such that said recess of said second needle is enclosed by said hollow first needle;

a first latch means selectively releasable from outside said guide sleeve for releasably holding said first spring in said energized mode;

a second latch means for releasably holding said second spring in said energized mode, said second latch means being releasable in response to and subsequent to release of said first spring; and

sequential energizing means operative to move said first needle head along said axis towards said rear guide sleeve end to cause said second latch means to hold said second spring in said energized mode, and subsequently to move said second needle head along said axis towards said rear guide sleeve end to cause said first latch means to hold said first spring in said energized mode.]

Claim 15 Yes_ or No ✓

(Infringes) (Does Not Infringe)

Claim 16. [A tissue sampling device comprising]:

a guide sleeve having front and rear guide sleeve ends and defining a longitudinal axis extending between

said front and rear guide sleeve ends, said front guide sleeve end having an opening therethrough;

a hollow first needle positioned within said guide sleeve and extendible from said opening, said hollow first needle being movable along said axis;

a second needle extending through said hollow first needle and movable along said axis, said second needle having a tip which is extendible from said hollow first needle and said opening, and said second needle further including a tissue sample receiving recess;

a first needle head coupled to said hollow first needle and mounted within said guide sleeve for movement along said axis to move said hollow first needle along said axis;

a second needle head coupled to said second needle and mounted within said guide sleeve for movement along said axis to move said second needle along said axis;

a first spring disposed within said guide sleeve and operatively associated with said second needle head, said first spring being capable of being placed into an energized mode to store energy, and said first spring being releasable from said energized mode to propel said second needle head along said axis towards said opening, such that said tip of said second needle is extended from said hollow first needle, whereby a tissue sample can be captured within said recess;

a second spring positioned within said guide sleeve and operatively associated with said first needle head, said second spring being capable of being placed

into an energized mode to store energy, and said second spring being releasable from said energized mode to propel said first needle head along said axis towards said opening, said hollow first needle being extended from said opening such that said recess of said second needle is enclosed by said hollow first needle;

a first latch means selectively releasable from outside said guide sleeve for releasably holding said first spring in said energized mode;

a second latch means for releasably holding said second spring in said energized mode; said second latch means being releasable in response to and subsequent to release of said first spring; and

energizing means operative to move said first needle head and said second needle head along said axis towards said rear guide sleeve end to cause said first latch means to hold said first spring in said energized mode and to cause said second latch means to hold said second spring in said energized mode, said energizing means being selectively operative to move said first needle head but not said second needle head towards said rear guide sleeve end, whereby said hollow first needle is selectively retractable to expose said tissue sample receiving means in said second needle.]

Claim 16 Yes_ or No ✓

(Infringes) (Does Not Infringe)

17. Do you find, by a preponderance of the evidence, that M3 SYSTEMS actively and knowingly induced others to infringe either or both of the following claims of the '308 patent as interpreted by the Court:

Claim 15 Yes_ or No ✓

(Induced) (Did Not Induce)

Claim 16 Yes_ or No ✓

(Induced) (Did Not Induce)

QUESTIONS CONCERNING WHETHER OR NOT M3 SYSTEMS HAS WILLFULLY INFRINGED C.R. BARD'S '308 PATENT

Answer Question No. 18 as to only those claims of the '308 patent you found infringed in response to Question Nos. 16 or 17 above, if any:

18. If you found, in response to question nos. 16 and/or 17 that any of Claims 15 and/or 16 were infringed, do you find, by clear and convincing evidence, that Defendant-Counterclaimant's infringement of same was willful?

ANSWER: Yes_____ or No_____

DAMAGE VERDICT FOR INFRINGEMENT OF BARD'S '056 PATENT WITH RESPECT TO THE ORIGINAL ACN OR SACN NEEDLES

To be answered only if you found infringement in response to question 13.

19. We, the jury in this cause, find the damages to be awarded to Plaintiff-Counterdefendant BARD arising out of Defendant-Counterclaimant M3 SYSTEMS' infringement of U.S. Patent No. RE 34,056 with respect to the original ACN or SACN needles to be in the amount of $_____.

DAMAGE VERDICT FOR INFRINGEMENT OF BARD'S '056 PATENT WITH RESPECT TO THE CURRENT ACN OR SACN NEEDLES

To be answered only if you found infringement in response to Question 14.

20. We, the jury in this case, find the damages to be awarded to Plaintiff-Counterdefendant Bard arising out of Defendant-Counterclaimant M3 Systems' infringement of U.S. Patent No. RE 34,056 with respect to the current ACN or SACN needles, to be in the amount of $_____.

DAMAGE VERDICT FOR INFRINGEMENT OF BARD'S '308 PATENT

To be answered only if you found infringement in response to questions 16 or 17.

21. We, the jury in this cause, find the damages to be awarded to Plaintiff-Counterdefendant BARD arising out of Defendant-Counterclaimant M3 SYSTEMS' infringement of U.S. Patent No. 4,944,308 to be in the amount of $_____.

_____

SPECIAL JURY INTERROGATORIES CONCERNING M3 SYSTEMS' ANTITRUST CLAIMS

The following questions seek your specific findings concerning whether M3 Systems has proved that Bard by its alleged anticompetitive conduct has either monopolized or attempted to monopolize any or all of the three relevant markets alleged by M3 Systems. You may find

that M3 Systems has proved one, two, three, or no relevant markets. Please answer the questions in *all* four sections (A-D) below.

A. Fully Automated Biopsy Gun and Needle Systems

1. Do you find that M3 Systems has proved by a preponderance of the evidence that there is a relevant product market for fully automated biopsy gun and needle systems?

ANSWER: Yes ✓ or No _

2. If your answer to No. 1 is "Yes", do you find that M3 Systems has proved by a preponderance of the evidence that Bard has monopoly power in the product market for fully automated biopsy gun and needle systems?

ANSWER: Yes ✓ or No _

3. If your answer to No. 2 is "Yes", do you find that Bard willfully acquired or maintained such monopoly power through restrictive or exclusionary conduct?

ANSWER: Yes ✓ or No _

4. If your answer to No. 2 or No. 3 is "No", do you find that M3 Systems has proved by a preponderance of the evidence that Bard's conduct created a dangerous probability that Bard would obtain monopoly power in the product market for fully automated biopsy gun and needle systems?

ANSWER: Yes _ or No _

5. If your answer to No. 4 is "Yes", do you find that Bard engaged in restrictive or exclusionary conduct with the conscious object of acquiring monopoly power in the market for fully automated biopsy gun and needle systems?

ANSWER: Yes ✓ or No _

B. Fully Automated Reusable Biopsy Guns

6. Do you find that M3 Systems has proved by a preponderance of the evidence that there is a relevant product market for fully automated reusable biopsy guns?

ANSWER: Yes ✓ or No _

7. If your answer to No. 6 is "Yes", do you find that M3 Systems has proved by a preponderance of the evidence that Bard has monopoly power in the product market for such reusable biopsy guns?

ANSWER: Yes ✓ or No _

8. If your answer to No. 7 is "Yes", do you find that Bard willfully acquired or maintained such monopoly power through restrictive or exclusionary conduct?

ANSWER: Yes ✓ or No _

9. If your answer to No. 7 or No. 8 is "No", do you find that M3 Systems has proved by a preponderance of the evidence that Bard's conduct created a dangerous probability that Bard would obtain monopoly power in the product market for such reusable biopsy guns?

ANSWER: Yes _ or No _

10. If your answer to No. 9 is "Yes", do you find that Bard engaged in restrictive or exclusionary conduct with the conscious object of acquiring monopoly power in the market for such reusable biopsy guns?

ANSWER: Yes ✓ or No _

C. Replacement Needles for Fully Automated Reusable Biopsy Guns

11. Do you find that M3 Systems has proved by a preponderance of the evidence that there is a relevant product market for replacement needles for fully automated reusable biopsy guns?

ANSWER: Yes ✓ or No _

12. If your answer to No. 11 is "Yes", do you find that M3 Systems has proved by a preponderance of the evidence that Bard has monopoly power in the product market for such replacement needles?

ANSWER: Yes ✓ or No _

13. If your answer to No. 12 is "Yes", do you find that Bard willfully acquired or maintained such monopoly power through restrictive or exclusionary conduct?

ANSWER: Yes ✓ or No _

14. If your answer to No. 12 or No. 13 is "No", do you find that M3 Systems has proved by a preponderance of the evidence that Bard's conduct created a dangerous probability that Bard would obtain monopoly power in the product market for such replacement needles?

ANSWER: Yes _ or No _

15. If your answer to No. 14 is "Yes", do you find that Bard engaged in restrictive or exclusionary conduct with the conscious object of acquiring monopoly power in the market for such replacement needles?

ANSWER: Yes ✓ or No _

D. **Injury and Damage**

16. If you answer "YES" to *any* of questions 3, 5, 8, 10, 13 *or* 15, do you find that M3 Systems has proved by a preponderance of the evidence that it has been injured or has suffered any loss as a direct result or likely consequence of any of the restrictive or exclusionary acts that you have found?

ANSWER: Yes ✓ or No _

17. If your answer to question 16 is "YES," in what amount do you find that M3 Systems has been damaged?

$1,500,000.00

The preceding determinations and verdicts are herewith submitted by the jury in the above-captioned matter as of the date indicated below.

September 28, 1995
Chicago, Illinois

/s/ Jackie L Anderson
Foreperson

/s/ Karen L. Illegible

/s/ Harold L. Illegible

/s/ Barbara J. Illegible

/s/ Christine J. Neubauer

/s/ Frederick G. Wagner

/s/ Nick Illegible

/s/ Illegible

**Bard Gynecology &
Radiology Division**

10115 Highway 142
Covington, Georgia 30209
Phone: 404/784-6700
Fax: 404/784-6704

To: Jeanne Marie Leahy

Company:

Fax Number: 784-6908

From: Ken Eakin

Date: March 1, 1994

Subject: Biopty

Number of Pages: 18 (including cover page)

**FOR ADDRESSEE ONLY
PLEASE DELIVER IMMEDIATELY**

DEFENDANT'S
EXHIBIT
DTX-904

**CONFIDENTIAL
ATTORNEY'S EYES ONLY**

B 0053488

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A 15099

[Spec. Prod. & Radiology]

BARD UROLOGICAL DIVISION
MAINTENANCE PROJECT INITIATION REQUEST

PROJECT NUMBER: _____

AUTHORIZATION DATE: _____

PROJECT NAME: 001400 Biopty Device: Dual Configuration for Customer Preference

REQUEST ORIGINATOR: Joe Rothstein

PRODUCT MANAGER: Ken Eakin/J.M. Leahy

(Maintenance Project Criteria: frozen design and process (e.g., involve existing components, no additional design effort requirements, etc.); no APE requirements; and no regulatory submission requiring a clinical study.

PROJECT TYPE:
[ ] Line Extension
[ ] Process Change
[ ] Change in Vendor
[ ] Product Change
[ ] Specification Correction
[X] Other

PROJECT DESCRIPTION AND OBJECTIVES: To offer customers choice in the application of the rear slide in the BIOPTY Gun of the old (slide) (carriage) before July, 1993, or new (slide) (carriage) after July, 1993.

[ ] CHECK IF ATTACHMENTS ARE SUPPLIED (submit technical documentation, purpose, drawing, etc. where appropriate.

PROJECT INITIATION APPROVALS:

PROJECT TYPE (PLEASE INITIAL)

MAJOR MAINTENANCE DATE

PROJECT INITIATION APPROVALS

R & D GROUP MANAGER

MARKETING DIRECTOR

MAINTENANCE TEAM LEADER

REGULATORY AFFAIRS MANAGER

QUALITY ASSURANCE DIRECTOR

AME MANAGER

V.P. OPERATIONS

V.P. REG. AFFAIRS/OA

V.P. FINANCE

MAINTENANCE PROJECT TEAM APPROVAL OF COMPLETED PROJECT:

AME _____ DATE _____

FINANCE _____ DATE _____

MANUFACTURING _____ DATE _____

MATERIALS MANAGEMENT ____ DATE _____

QUALITY ASSURANCE _____ DATE _____

DIVISION PRESIDENT _____ DATE _____

CONFIDENTIAL
ATTORNEY'S EYES ONLY
B 0053489

A 15100

CONFIDENTIAL

SITUATION ANALYSIS

THE FOLLOWING IS A REVIEW OF THE IMPACT OF THE BEST BUY PROGRAM

1. ASSESSMENT OF BEST BUY GUN PROMOTION PROGRAM

BEST BUY GUN REVENUE (GROSS SALES)

GUNS	#	ASP	$ REV	$ COST	$ GP	% GP
RE-FURBISH	83	$300	24,900	12,450	12,450	50
RE-PAIRED	18	$250	4,500	1,800	2,700	60
NEW (SOLD)	180	$1500	269,495	85,000	185,000	67
NEW (EXC/NC)	467	0	0	220,424	(220,424)	0
TOTALS	746	$683	298,895	319,674	(20,000)	

IN ORDER TO MAINTAIN OUR POSITION IN THE DISPOSABLE CORE NEEDLE MARKET, WE SPENT $220,424 IN NEW EXCHANGED GUNS. THIS HAS ALLOWED US TO MAINTAIN OUR MARKET SHARE AND BLUNT COMPETITIVE INROADS WHERE NEW COMPETITIVE GUNS WERE OFFERED AT DISCOUNTS OR NO CHARGE IN ORDER TO TAKE OUR CUSTOMERS AWAY.

WE ALMOST MAINTAINED OUR NEEDLE VOLUME MARKET SHARE AND IN DOING SO, MADE IT DIFFICULT FOR COMPETITION TO MAKE SERIOUS INROADS INTO OUR ACCOUNTS. OF THE 746 NEW,

REFURBISHED AND REPAIRED GUNS, [sic] WERE MODIFIED TO THE NEW REAR SLED.

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B 0053490

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2. TOTAL GUNS IN MARKET

MANUFACTURER	#GUNS (EST.)	LISTS
BARD-OLD	2600	1500
BARD-NEW MODIFIED	1700	1500
MANAN	700	750
BIP-OLD	40	900
BIP-NEW	10	900
TOTAL	5,050	

THERE STILL REMAIN MANY OLD, UNMODIFIED BIOPTY GUNS IN THE MARKET AS WELL AS A SIGNIFICANT NUMBER OF OLD MANAN GUNS THAT CAN ACCOMMODATE OUR NEEDLE. BIP'S NEW ENTRY IS BOTH A NEW NEEDLE HUB CONFIGURATION AND GUN SYSTEM. IT IS STILL TOO NEW TO ESTIMATE IT'S MARKET PENETRATION.

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B 0053491

A 15102

3. BEST BUY NEEDLE UNITS, REVENUE, COST RESULTS.

WE SACRIFICED MARGINS TO MAINTAIN OUR POSITION AND KEEP CUSTOMERS BY MATCHING COMPETITIVE PRICING.

IN THE FOLLOWING TABLE THE CUSTOMERS WERE THE FOLLOWING:

- NEW – NEW CUSTOMERS NOT PREVIOUSLY BARD CUSTOMERS.
- RENEW – CUSTOMERS WHO RENEWED OLD CONTRACTS WITH THE BEST BUY.
- BLUE – CUSTOMERS IN 1991, WERE LOST IN 1992, AND REGAINED IN 1993.
- TO KEEP – CUSTOMERS WHO WERE ACCOUNTS BUT WE HAD TO OFFER INCENTIVE TO KEEP SUCH AS WITH PRICE MATCHING.

BEST BUY NEEDLE REVENUE (GROSS SALES)

	ACCOUNTS	COMM CASES	REVS (000)	COST (000)	GP$ ASP	GP (000)	%
NEW	189	6,859	613	446	89.34	167	27
REN	177	5,412	860	352	158.90	508	59
BLUE	33	882	114	57	126.88	57	60
TO KEEP	9	1,009	109	66	107.76	43	39
TOTALS	388	14,162	1,696	921	121.22	775	44

BEST BUY NEEDLE COMMITMENTS ARE 141,620 NEEDLES, OR 77% OF THE 183,000 NEEDLES SOLD IN 1993.

THE BEST BUY REVENUE COMMITMENTS AMOUNT TO ONLY 55% OF GROSS SALES FOR 1993 AND GROSS MARGINS WILL AVERAGE ABOUT 44% VS. 61% IN 1993 ACTUAL RESULTS.

WITH BEST BUY ACCOUNTS REPRESENTING OVER HALF OF OUR BUSINESS IT IS LIKELY THAT 1994 GROSS MARGINS WILL BE BELOW 1993 LEVELS.

- NEEDLE COMPETITION

SEVERAL PREVIOUSLY INFRINGING NEEDLE MANUFACTURERS HAVE WITHDRAWN THEIR OLD HUB NEEDLES AND HAVE REPLACED THEM WITH NEW HUBS THAT DO NOT, IN THE OPINION OF THE ENGINEERING GROUP, INFRINGE OUR PATENTS. THE GUN AND NEEDLE COMPATIBILITY IS OUTLINED BELOW. [The preceding sentence was redacted by Bard when this was originally produced.]

	BARD GUN		MANAN	BIPGUN	
	OLD	NEW	GUN	OLD	NEW
NEEDLES					
MANAN					
OLD*	Y	Y	Y	Y	N
NEW	Y	N	Y	Y	N
PROMEX					
OLD*	Y	Y	Y	Y	N
NEW	Y	N	Y	N	N
MD-TECH					
OLD*	Y	Y	Y	Y	
NEW	Y	N	Y	Y	
CORE*	Y	Y	Y	Y	
MEDITECH*	Y	Y	Y	Y	N
BARD	Y	Y	Y	Y	N

- *REMOVED FROM MARKET

- MD-TECH AND PROMEX HAVE REENTERED WITH MODIFIED HUB

THIS TABLE POINTS TO THE FACT THAT THERE ARE STILL SEVERAL COMPETITIVE NEEDLES AVAILABLE WHICH ARE COMPATIBLE WITH OLD BARD GUNS, THE MORE AGGRESSIVELY WE REPLACE THESE

GUNS THE LESS OPPORTUNITY FOR COMPETITIVE NEEDLES TO MAKE INROADS.

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- RANGE OF NEEDLE PRICES AS SURVEYED FROM TELESALES

	LOW	NORMAL	EST. VOLUME	%
• MANAN	$7.95	$13.00-$15.00	75,000/YR	22
• CORE*	$6.75	$ 6.75-$ 9.00	20,000/YR	6
• MD-TECH**	$8.00	$ 9.50-$19.00	25,000/YR	7
• PROMEX**	$8.00	$ 9.50-$19.00	15,000/YR	4
• BARD	$7.95	$12.00-$24.00	183,000/YR	53
• BIP	$8.00	$ 9.50-$15.00	15,000/YR	4
• MEDI-TECH	$9.50	$ 9.50-$15.00	15,000/YR	4

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* REMOVED FROM MARKET

** BASED ON PREVIOUS PRICING HISTORY

- CUSTOMER/MARKET BREAKDOWN

SOURCE: SURVEY BY TIM PRUITT 8-93

VOLUME CASES/ YEAR	% OF CUSTOMERS	% OF REVENUE	GOLD STD %
0-5	35%	7%	0
6-12	27%	15%	0
13-24	20%	23%	5
25-36	8%	16%	10
37-48	4%	10%	15
49+	6%	29%	20-40

• SUMMARY OF BARD NEEDLE UNIT REVENUE

	1992*	
Units	Dollars	ASP
189,900	3,233,189	$17.03

	1993*	
Units	Dollars	ASP
183,000	3,081,429	$16.83

*GROSS DOLLARS PER LEN KOZENY

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PROPOSAL

I. OBJECTIVES

- PLACE NEW BARD GUNS IN MARKET TO DISPLACE COMPETITOR'S GUNS
- NEEDLE PRICING TO DISCOURAGE COMPETITION

- POSITION BARD FOR FUTURE BIOPSY DOMINANCE
  - MAKE IT DIFFICULT FOR MANAN TO COMPETE
  - LOSE/DRAW MANAN SUIT-STRATEGICALLY PRICED AND PLACED
- POSITION BARD AS LEADER IN CORE TISSUE BIOPSY
  - QUALITY OF BARD PRODUCTS DEMANDS HIGHER PRICE
  - PROFESSIONAL, FLEXIBLE MARKET LEADER
- WORK WITHIN BUDGET CONSTRAINTS (NO BUDGET FOR BEST BUY)
- POSITION BARD TO KEEP CUSTOMERS AND BRING THEM BACK TO REGULAR PRICING STRUCTURE

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II. STRATEGIES

A. TARGET KEY SEGMENTS

- SMALL VOLUME (6-11 CASE) ACCOUNTS
- MANAN ACCOUNTS
- "CORE" ACCOUNTS
- OLD BIOPTY ACCOUNTS WHO HAVE SWITCHED TO COMP. NEEDLES
- ACCOUNTS COMING OFF BEST BUY

B. GENERAL PROPOSAL

- PROVIDE A FAIR PRICE STRUCTURE
- PROVIDE INCENTIVE TO SWAP COMPETITOR'S GUNS AND SWAP OR CONVERT OLD BARD GUNS
- FLEXIBLE PRICING TO MATCH COMPETITION
  - COMPETITION: MANAN, BIP, MD-TECH, PROMEX
- TELESALES ACTIVITY TO ALL TARGETED ACCOUNTS
- DIRECT SALES ACTIVITY TO LARGE (CURRENTLY COVERED) TARGETED ACCOUNTS

III. TACTICS

A. PROPOSED NEW PRICE STRUCTURE

- LOWERS VOLUME DISCOUNTS TO INCREASE ELIGIBILITY
- PRICES OVERALL WILL CONTINUE TO BE HIGHER THAN COMPETITION

1994 COMPETITIVE NEEDLE PRICING STRUCTURE

BEST BUY	DISC %	NEW PROG	DISC %
1-12	0	1-5	0
13-24	5	6-24*	5
25-36	10	25-36	10
37-48	15	37-48	15
49-60	20	49-60	20
61-100	25	61-100	25
101-300	30	101-300	30
301-500	35	301-500	35
501+	40	501+	40

- *NEW, LOWER DISCOUNT AVAILABLE TO SMALLER CUSTOMER

- BY LOWERING MINIMUM ORDER QUANTITY FROM 12 TO 6, AN ADDITIONAL 15% IN REVENUE FROM COULD BE GENERATED FROM CUSTOMERS NOT QUALIFYING FOR DISCOUNTS.

- EXISTING BARD CUSTOMERS CURRENTLY UNDER OTHER BARD DISCOUNT PROGRAMS ARE NOT ELIGIBLE UNLESS AND UNTIL THOSE PROGRAMS EXPIRE UNDER THEIR INDIVIDUAL TIMETABLES.

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B. PRICE MATCHING PROGRAM

- IN THE EVENT OF COMPETITIVE SITUATIONS OUTSIDE THESE GUIDELINES, PRICE MATCHING WILL BE IMPLEMENTED ON A CUSTOMER BY CUSTOMER BASIS. THIS MATCHING WILL REQUIRE:

- A COPY OF A QUOTE GIVEN TO A POTENTIAL CUSTOMER
- DOCUMENTATION OF COMPETITIVE SITUATION BY CUSTOMER
- APPROVAL BY NATIONAL SALES MANAGER AND/OR PRODUCT MANAGER
- PROGRAM WILL BE ADMINISTERED BY CUSTOMER SERVICE AND TELESALES, AS WELL AS DIRECT SALES FORCE
- CUSTOMER MUST SIGN 1 YEAR EXCLUSIVE NEEDLE CONTRACT
- ANY ONE YEAR NEEDLE COMMITMENT MUST INCLUDE AN OFFER OF A GUN
- CUSTOMER MUST PROVIDE PRICE, VOLUME AND OTHER DATA FOR US TO MATCH OUR PRODUCTS AND PRICES, DATA MUST ALSO INCLUDE LENGTH OF OFFER BY COMPETITOR AND COMMITTED VOLUME

PRICE MATCHING APPLIES ONLY TO ACTIVE COMPETITORS INCLUDING:

- MANAN
- MD TECH
- BIP
- PROMEX NEW NEEDLE

C. 1994 BIOPTY GUN PROMOTION

- IF THE CUSTOMER IS A NEW CUSTOMER AND HAS AN OLD, UNMODIFIED BARD GUN OR A COMPETITIVE GUN, WE WILL SWAP OUT THEIR AND SELL THEM A NEW GUN FOR A CHARGE OF $500 AND BARD WILL REFURBISH THE CUSTOMER'S OLD GUN AT NO CHARGE WITH A SIGNED ONE YEAR NEEDLE COMMITMENT.
- IF A NEW CUSTOMER HAS NO GUN A $700 CHARGE PER GUN WILL BE ASSESSED
- IF A NEW CUSTOMER HAS AN OLD BARD GUN, THE GUN WILL BE REFURBISHED AND RETURNED TO CUSTOMER FOR NO CHARGE.
- ALL OFF-LIST PRICING OF GUNS CONTINGENT ON CUSTOMER COMMITMENT TOA ONE (1) YEAR NEEDLE CONTRACT.
- IF CUSTOMER DOES NOT MEET MINIMUM NEEDLE COMMITMENT OR WISHES TO PURCHASE GUNS WITHOUT NEEDLE COMMITMENT, A CHARGE OF $1500 WILL APPLY PER GUN.

CUSTOMER GROUP	OFFER
NEW, WITH BARD OR COMPETITIVE GUN	$500 GUN; SWAP AND REFURB @ NO CHARGE
NEW, NO GUN	$700 PER GUN
NEW, OLD GUN, DOESN'T WANT NEW GUN	REFURB, N/C

ALL OFFERS ARE VALID ONLY WITH ONE YEAR SIGNED NEEDLE COMMITMENT.

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D. IMPLEMENTATION

- THE PROGRAM WILL COMMENCE ON OR BEFORE MARCH 1, 1994
- TELESALES/CUSTOMER SERVICE WILL BEGIN TO CONTACT ALL CUSTOMERS BEGINING MARCH 1, 1994
  - FAX MESSAGE SENT ON MARCH 1
  - CUSTOMERS CONTACTED BY PHONE ON MARCH 1
  - CUSTOMERS THAT WILL BE CONTACTED FIRST INCLUDE CORE MEDICAL, MANAN MEDICAL, AND OLD BARD CUSTOMERS NOT CURRENTLY PURCHASING OUR NEEDLES.
- BEGINNING AFTER MARCH 1, THE DIRECT SALES FORCE WILL CONTACT ACCOUNTS CURRENTLY COVERED BY THE DIRECT SALES FORCE AND ACCOUNTS THAT QUALIFY FOR THE OFFER.

E. TERMS AND CONDITIONS

- ALL TERMS AND CONDITIONS OF SALE LISTED IN THE CURRENT PRICE LIST WILL BE FOLLOWED

- BARD OR CUSTOMER CAN CANCEL THE AGREEMENT WITH THIRTY (30) DAYS WRITTEN NOTICE
- CUSTOMER IS REQUIRED TO MEET MINIMUM ORDER WITHIN ONE (1) YEAR OF SIGNING
- DISCOUNTS FOR GREATER QUANTITIES THAN CONTRACTED ARE AT THE DISCRETION OF BARD

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F. COST AND RETURN OF PROGRAM: PROPOSED FOR ONE YEAR BEGINNING MARCH 1, 1994 THROUGH FEBRUARY 28, 1995.

A. PROJECTED NEW NEEDLE CUSTOMERS

#CUST	CASES	SALES	COST	GP$	GP%
300	2,400	$291,000	$156,000	$135	46

ASSUMPTIONS:

- 500 POTENTIAL NEW CUSTOMERS CURRENTLY PURCHASING LESS THAN 12 CASES PER YEAR, BUT MORE THAN 5
- 60% HIT RATE THROUGH TELESALES/ DIRECT SALES EFFORT
- AVG # OF CASES PURCHASE PER YEAR PER ACCOUNT-8
- NEW CUSTOMERS PURCHASE @$121.22 PER CASE ASP

B. GUNS

NEW	#	PRICES	REV$	COST$	GP$	GP%
@$500	216	500	108,000	101,952	6,048	.01
@$700	84	700	58,000	39,648	18,352	32

ASSUMPTIONS:

- 500 POTENTIAL CUSTOMERS
- 60% HIT RATE FROM TELESALES/DIRECT SALES
- SAME RATIO OF NEW GUNS AT LIST AND EXCHANGED FROM 1993 BEST BUY PROGRAM

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PROJECTED REVENUE IN NEW PROGRAM

GUNS	#	ASP	$ REV	$ COST	$ GP	% GP
REFURB	150	N/C	0	22,500	(22,500)	(22,500)
REPAIR	20	250	5,000	1,800	3,200	64
NEW (EXCH)	216	500	108,000	101,952	6,048	.01
NEW (SOLD)	84	700	58,800	39,648	19,152	33
TOTALS	360		171,800	165,900	5,900	3

G. MEASUREMENT

UNITS, REVENUE, GUN PLACEMENTS, ETC. WILL BE TRACKED MONTHLY.

- REVENUE GENERATED BY NEW GUN SALES, BEST BUY COST THE PROJECT IN EXCESS OF $220,000 IN THE 10 MONTHS IT WAS IN EXISTENCE. AT THE VERY LEAST, WE SHOULD EXPECT TO BREAK EVEN BETWEEN THE COST OF THE GUNS AND THE REVENUE GENERATED ON SALES OF GUNS AT $500.

  GUNS SOLD AT $700 SHOULD GENERATE A 33% GP

  GUNS SOLD AT LIST PRICE SHOULD GENERATE A 66% GROSS PROFIT.

  NEEDLES OVERALL SHOULD CONTINUE TO MAINTAIN OUR CURRENT MARKET SHARE AND HELP US GAIN NEW CUSTOMERS THAT HAVE NOT BEEN PURCHASING IN THE PAST FEW MONTHS AND YEARS. NEEDLE GP SHOULD BE AT LEAST 46% OF REVENUE, WHICH IS EQUAL TO THE BEST BUY PROGRAM.

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CUSTOMERS COMING OFF BEST BUY CONTRACTS

BEGINNING IN MARCH, SEVERAL ACCOUNTS THAT WERE SIGNED UP IN THE BEST BUY PROGRAM WILL HAVE THEIR CONTRACTS EXPIRE. THEY SHOULD BE OFFERED THE FOLLOWING CONTRACTS.

- RENEWAL CUSTOMERS THAT ARE NOT "PRICE MATCHED" CUSTOMERS FROM 1993 SHOULD BE RENEWED AT THE EXISTING PRICE QUOTE IN THE NEW PROGRAM ACCORDING TO ANNUAL CASE USAGE.
- CUSTOMERS WHO WERE RETAINED IN THE BEST BUY DUE TO "PRICE MATCHING" SITUATIONS SHOULD BE OFFERED THE SAME PRICE STRUCTURE AS ALL OTHER CUSTOMERS.
- ANY CUSTOMER WHO REFUSES TO BE RAISED TO THE PROGRAM AND HAS BEEN QUOTED A COMPETITIVE PRICE CAN BE MATCHED UNDER THE NEW PROGRAM
- ALL GUN SWAP AND REFURBISHING WILL BE UNDER GUN PROMOTION OUTLINE
- ANY PRICE MATCHING MUST CONFORM TO A VOLUME COMMITMENT FOR A SPECIFIC PERIOD

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Bard Urological Division

Proj. #3290
File

MEMO TO: L. Salgaeiro* G. Teague*
B. Mirsky* R. Griffith*
D. McKinley B. Norton*
B. Graham J.M. Leahy*
D. Burton* B. Wall*
K. Dye* J. Klimbach*
M. Waller*

cc: JJK – info
Mike – info

FROM: G. Thompson

DATE: July 8, 1993

SUBJECT: *Biopsy Meeting Minutes*

A meeting was held on July 2nd in order to bring all of the parties involved to the same understanding of the current status of our Biopsy business and to formulate future strategies.

An agenda was prepared before the meeting and although not necessarily followed to a tee, I will still use it as my basis for organizing the meeting minutes.

* Individuals in attendance.

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DTX-357

- *Inventory Update:* Kevin Dye presented an analysis of projected inventory balances by F.G. # for year ending 1993. These are based on current levels plus purchase commitments less anticipated sales demand based on current forecasts. The total exposure by year-end could be $2.7 million. Of this total $1.7 million is in the Holgrath needles which are neither centimeter marked nor etched tipped.

  Kevin and Lou noted that AMI could rework these needles with centimeter markings and etched tips for approximately $.75 per needle. The group determined this would be a worthwhile investment, particularly to reopen the International market, in which the etched tip is basically a requirement, and secondly as replacement inventory for Inrad Radiology customers of Accucore II, once the initial inventory purchased from Inrad is depleted.

  Action Items: Kevin is to write a memo to Alfonso/Brett on inventory availability. Group agreed that initial shipment of 50,000 needles should be sent to AMI for rework. Brett to determine extent of Intercompany interest by next meeting.

- *Current Vendor Update/Controlling Steel Supply:* Due to our current inventory position we are basically putting Holgrath and Harmac on extended hold through the end of the year as far as any additional production. Holgrath is stating that we owe them $25K for obsoleted hub inventory.

  Approximately 30-40K units of inventory are being purchased from Inrad as part of an asset agreement. These are to be sold off to Inrad customers and are not intended to be sold to current Bard accounts.

  Lou and Kevin have met with both AMI and Holgrath. The general message from both is that even though we certainly can't tell a supplier who to sell to, they

understand the current situation and both say they are no longer supplying needles to other companies and are dedicated to Bard.

A14820

Core apparently bought their own machines to grind needles, but that has not been successful. Question raised by John Klimbach as to whether Radi could be supplying steel to anyone.

Core and Promex were both analyzed by Burt and written off as possible acquisition or supplier candidates.

Action Items: Gary Thompson will review Radi contract to determine if working hinders them from selling steel. Gary and Kevin to determine if credit to be given to Holgrath on obsolete hub inventory.

- *Gun Modification Update:* Green form was signed 7/1/93 on this project. There are 196 guns in inventory. The gun modification is still an issue in the International arena. 250 of the old guns have been put in a separate inventory account for their access in case regulatory dictates the modification can't be initially used. Donna Burton suggested we reduce that amount based on current Intercompany forecasts.

  Resolution on this by 7/15 between Donna and International Marketing. Per Rich Griffith the cost of the gun modification will be approximately $125K. The new gun is expected to cost between $25-$50 more than the old model.

- *Manan Gun Update/Legal Update:* Per Bill Norton, legal opinion not yet received although verbal indications are that it is positive. No opinion yet on the needle. [The preceding sentence was redacted by Bard without notice when it was originally produced.]

It was mentioned that Cook may have a new motorized gun.

Discussion was held concerning companies being allowed to dump their inventories. Legally they can sell off inventory although there may be an issue as to whether it was manufactured before or after the receipt of our letter. Short term this is a significant issue.

- *Product Testing (Promex/Core):* As noted previously, these vendors will not be pursued for acquisition or future supply.
- *Best Buy Update:*

BRD:
- 23 New customers
- 22 Renewals
- 10 Regains From '91
- 7 Saves (were about to lose)
- 62 Total

Total of 121 new gun commitments (P.O.'s in house)

BUD:
- 12 New customers
- 23 Renewals
- 12 Regains
- 4 Saves
- 56 Total

Total of 72 new gun commitments.

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Considering the program has only been in place a little more than a month, Gary Teague noted that the plan was working. Donna Burton felt both plans could

still be tweaked. As an example, BUD should drop the 3 case minimum for competitive pricing. BRD should revisit their pricing based on volume levels.

Action Item: Both Marketing groups agreed to revisit pricing and prepare written statements of modification by 7/15. (Jeanne Marie Leahy and Gary Teague)

- *Inrad Update:* Asset agreement signed 7/1. BRD will get sales credit for anything Inrad drop ships until we can handle out of Covington. The invoices will come to us and we will be responsible for collection. BRD will be receiving at least 3 months inventory of every size needle.

  Action Item: Neal Taylor to analyze specific inventory levels for all products received.

  Note: Specs and any other technical issues with this inventory onload were handled via a maintenance project.

- *BIP Update:* Not covered.

- *Marketplace Reviews:*

  BUD – Per Mike Waller, very little activity. This is not an incentive category in BUD's Commission Plan. Needle commitments are primarily being achieved through Telesales.

  BRD – Per Gary Teague, sales reps are actively pursuing new business. Reps are shifting to larger accounts, shifting more emphasis on mid-range admission hospitals to Telesales; would like to add two people to Telesales to support this shift.

  The feeling is that procedures are down from prior year, that hospitals are not carrying as much inventory and that business was lost to Manan.

- *International Options:* reviewed primarily in the context of renewed opportunity with reworked needles

that are centimeter marked and have etched tips. Action item previously noted for Brett Wall to follow-up with Alfonso and the applicable International Marketing Management [Multilingual labeling?]

- *Future Strategic Direction:*

  Burt layed out a 4-tiered strategy as follows:

  1) Maintain our leadership position in the market
  2) Give reasons to our competitors why they should not fight lawsuits
  3) Sacrifice in the short-term for long-term benefit
  4) Reduce our inventory position

Tactics discussed to help implement these strategies:

- *International* penetration strategy. Needles must be centimeter marked and etched tips. Investigate 2 tiered approach (lower cost unmarked, higher cost marked).
- *Domestic* – overall seems to be a lack of understanding as to what the true marker size is, and what kind of share we really possess. There is concern by BRD that Microvasive's ASAP is hurting us in the hospital where such procedures get reimbursed. Not an issue in the doctor's office per Mike.

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Possible tactics for BUD:

1) Revise sales incentive – short term programs
2) Possibility of bundling with other products

3) Needle giveaways with modified guns

4) Lowball pricing on volume commitments – target competitive accounts

5) Revisit Leadership ("Best Buy") Program.

Possible tactics for BRD:

1) Revisit Leadership ("Best Buy") Program

2) Direct Mails

3) Swap out strategy that focuses on competitors. Go after smaller customers with Telesales support. Donna mentioned whether we should turn over all Biopsy business to BRD. Mike Waller to follow up with Dave McKinley.

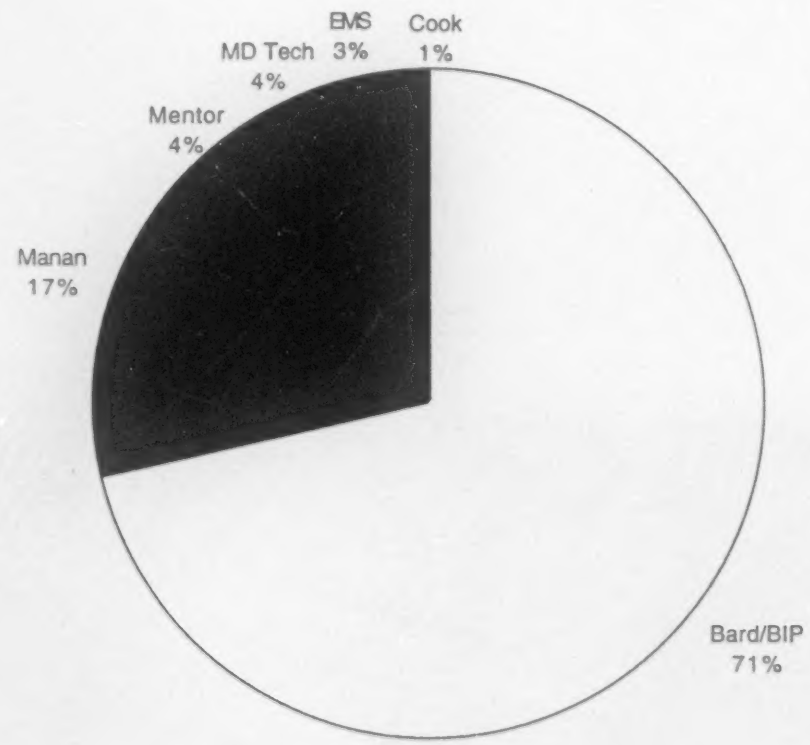
A follow-up meeting to monitor the progress of all action items and further resolve tactical strategy issues is scheduled for July 21st at 9:00am. You will receive more details on this in the near future.

Please let me know if you have a different interpretation of any of the points brought out in this summary or you feel anything of significance has been left out. There was an awful lot of information discussed in this meeting and since I would consider this business a high priority given our current situation, its essential we all agree on our *current status* and our *future direction*.

GT:wk

Replacement Needles for Reusable Biopsy Guns			
	1994 U	Share	HHI
Bard/BIP	367,465	71.2	5,063
Manan	86,045	16.7	278
Mentor	21,909	4.2	18
MD Tech	19,603	3.8	14
EMS	15,000	2.9	8
Cook	4,020	0.8	1
Bauer	1,385	0.3	0
Boston Sci	1,000	0.2	0
	516,427		
		HHI =	5,382

1994 Market Share in Units: Replacement Needles for Reusable Guns

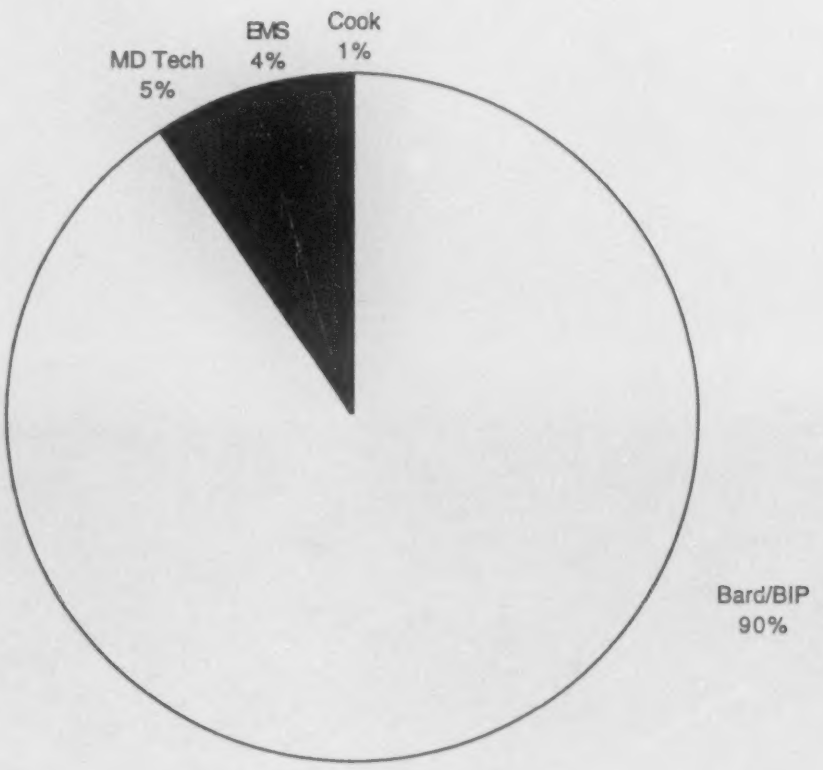


DEFENDANT'S EXHIBIT
DTX-1024G

Replacement Needles for Reusable Biopsy Guns
Manan and Mentor Sales Prorated

	1994 U	Share	HHI
Bard/BIP	464,581	90.0	8,093
MD Tech	24,784	4.8	23
BMS	18,964	3.7	13
Cook	5,082	1.0	1
Bauer	1,751	0.3	0
Boston Sci	1,264	0.2	0
	516,427		
		HHI =	8,131
		Change in HHI =	2,748

1994 Market Share in Units: Replacement Needles for Reusable Guns



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DEFENDANT'S EXHIBIT
DTX--1024H

DEFENDANT'S
EXHIBIT
DTX-309

BARD RADIOLOGY BUSINESS CENTER
KEY DIVISIONAL STRATEGIES

- Increase market share through patent infringement action and aggressive sales and marketing strategies.
- Rapidly expand core tissue biopsy into the hospital based radiology and ultrasound markets and diagnostic breast centers.
- Increase market share through new product introductions, line extensions, line modifications, distribution agreements and acquisition.
- Explore opportunities in emerging markets:

  Percutaneous Tissue Excisional Biopsy

  Interventional Neuroradiology Devices

  Central Venous Access Devices

  Arterial and Biliary Stents

  Removable Vena Cava Filters

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B 0031684

STATEMENT OF
OBJECTIVES, STRATEGIES AND TACTICS

BIOPSY PRODUCTS

Objective

Achieve annual sales of $18.8 million by 1996.

Strategy

Increase market share by leveraging our dominant market position, patent protection and product differentiation.

Tactics

Aggressively defend our Biopty and Monopty patents.

Implement price and product promotions and incentives designed to counter competitive threats.

Expand call point to include hospital based urology, nephrology, surgery, neurology, transplant centers and gastrointerology.

Through acquisition and in-house development continue to add line extensions and line modifications to completely serve the physicians automated core tissue biopsy needs.

Improve cost control through vertical integration into manufacturing.

Continue to work with imaging industry leaders and key physicians to promote core tissue biopsy in the breast.

Provide sales force with scientific support for continued conversion of FNAB and open surgical biopsies to automated core tissue biopsy.

Current Product

- Reusable Biopty instruments for core tissue sampling (11.5mm and 23mm needle penetrations).

- Disposable Biopty-Cut needles for core tissue sampling (14Ga., 16Ga., 18Ga., and 20Ga. needles in 10cm, 16cm and 20cm lengths; cm marked; with and without CT Spacers).

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- Disposable Monopty instruments for core tissue sampling (18g and 20g needles in 10cm, 16cm and 20cm lengths; 11 and 22 mm needle penetrations).
- CT Guide and CT Guide Accessory kits for precise needle guidance to a specific location within the body.
- Angiomed Ostycut needles for bone biopsy.

Future Products

- 14Ga. and 16Ga. Monopty when more tissue per biopsy is required.
- Inrad Accucore and Preset core tissue biopsy needles; state-of-the-art needle supply agreement.
- Coaxial guidance systems for Monopty and Biopty.
- Bauer-Temno semi-automatic core tissue biopsy instruments; light weight instrument for "close quarter" and CT guided biopsy.
- Percutaneous Excisional Biopsy Instruments and Systems.
- Smaller (close quarter) instruments for upright stereotactic mammography add-on systems.

Price

- Promote contracts utilizing "Gold Standard" and matched competitive prices.

Promotion

- Growing, dedicated, motivated and focused sales-force.
- Telesales for lead generation and follow-up.
- Focused literature, video and reprint distribution.
- Convention, seminar and symposia attendance.
- Personal relationship building with physicians.

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- Channel product development through thought leaders and high volume users of core tissue biopsy products.
- Increase utilization of market research.

Place

- Continue direct distribution to customers.

Position

- THE LEADER in core tissue biopsy research, development and marketing.

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B 0031687

Supreme Court, U.S.
FILED
APR 28 1999

No. 98-1572

IN THE

Supreme Court of the United States

OCTOBER TERM, 1998

M3 SYSTEMS,

Petitioner,

—v.—

C.R. BARD, INC.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

RESPONDENT'S BRIEF IN OPPOSITION

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PARTIES TO THE PROCEEDING

The names of all parties in the court whose judgment is sought to be reviewed appear in the caption of petitioner's conditional cross-petition for writ of *certiorari*.

Respondent is C.R. Bard, Inc. ("Bard"). Pursuant to Supreme Court Rule 29.6, respondent states that it has no parent company or subsidiaries.

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No. 98-1572

IN THE SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1998

M3 SYSTEMS, *Petitioner,*

v.

C.R. BARD, INC., *Respondent.*

RESPONDENT'S BRIEF IN OPPOSITION

I. STATEMENT OF THE CASE

M3 premises its conditional cross-petition for writ of *certiorari* on an alleged conflict between the Ninth and Federal Circuits regarding the evidence necessary to prove "sham" litigation antitrust liability (Pet. at 11-14) and, on the contention that the Federal Circuit's "newly-announced standard" would allow patent plaintiffs to "avoid all possibility of antitrust liability for bad faith patent enforcement." Pet. at 15-17. M3's arguments are completely without merit.

The Federal Circuit properly applied this Court's "objectively baseless" standard for a "sham" litigation set forth in *Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49 (1993) (*"PRE"*). The subjective standard from the old Ninth Circuit *Handgards* cases, which M3 resurrects to create a "conflict", was specifically rejected by the Court in *PRE*, and has been completely disregarded by subsequent Ninth

Circuit decisions. Further, the so-called "newly-announced standard" which M3 criticizes is based on an inaccurate characterization of the Federal Circuit's holding. M3 presents the Court with no compelling reason why its conditional cross-petition for writ of *certiorari* on the sham litigation issue should be granted.

A. *PRE*'s "Objectively Baseless" Standard For A Sham Litigation

In *PRE*, 508 U.S. at 60-61, the Court provided the standard for finding antitrust liability based on the commencement of a "sham" litigation:

> We now outline a two-part definition of "sham" litigation. First, the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits. . . . Only if challenged litigation is objectively meritless may a court examine the litigant's subjective motivation. Under this second part of our definition of sham, the court should focus on whether the baseless lawsuit conceals "an attempt to interfere *directly* with the business relationships of a competitor". . . . (citation omitted) (emphasis in original).

Further elaborating on the two-part definition, the Court stated:

> This two-tiered process requires the plaintiff to disprove the challenged lawsuit's *legal* viability before the court will entertain evidence of the suit's *economic* viability.

Id. at 61 (emphasis in original).

In arriving at this "two-part definition," the Court traced the development of the standard for determining immunity from antitrust liability. *Id.* at 56-60. The Court noted that an exception to antitrust liability for restraint of trade based upon immunity for "political activity" was first recognized in *Eastern Railroad Presidents Conf. v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961) ("*Noerr*"). *See PRE*, 508 U.S. at 56. The Court noted that *Noerr* withheld immunity when the political activity "'is a mere sham to cover . . . an attempt to interfere directly with the business relationships of a competitor.'" *Id.* (quoting *Noerr*, 365 U.S. at 144). The *PRE* Court then acknowledged that *California Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508 (1972) extended *Noerr* to cover the commencement of litigation. 508 U.S. at 57:

> We left unresolved [in *California Motor Transport*] the question presented by this case—whether litigation may be sham merely because a subjective expectation of success does not motivate the litigant. We now answer the question in the negative and hold that *an objectively reasonable effort to litigate cannot be a sham regardless of subjective intent.* (emphasis added) (footnote omitted).

The *PRE* Court further observed that the objective standard was consistent with its earlier decisions. *Id.* at 58-60.

The Ninth Circuit found that the antitrust defendant, Columbia, had probable cause to bring its lawsuit. *Columbia Pictures Indus., Inc. v. Professional Real Estate Investors, Inc.*, 944 F.2d 1525, 1531-32 (9th Cir. 1991). This Court held that the finding of probable cause precluded a conclusion that the litigation was objectively baseless. *PRE*, 508 U.S. at 63:

> Under our decision today, therefore, a proper probable-cause determination irrefutably demonstrates that an antitrust plaintiff has not proved the objective prong of the sham exception and that the defendant is accordingly entitled to *Noeer* immunity.

The Court supported the holding of the Ninth Circuit by acknowledging that the undisputed facts showed that Columbia enjoyed a valid copyright and noted that, under the holdings of two other circuit courts (the Third and the Seventh Circuits), Columbia may have prevailed on its legal theory. *Id.* at 64-65.

B. Evidence Presented At Trial Shows That M3 Infringed Bard's Patent

As the Federal Circuit observed, the "totality of the evidence" presented at trial by M3 in an attempt to show that Bard had engaged in "sham" litigation consisted of the testimony of a Bard engineer who did not feel that the original M3 needle infringed Bard's U.S. Patent No. RE 34,056 ("the '056 patent"), and of other Bard employees who told the engineer that M3 modified its original needle to a design that did not infringe (M3's current design). 55a-56a. There was no evidence that these employees had ever read the '056 patent or were knowledgeable regarding an analysis of infringement under the doctrine of equivalents. 56a. *See generally Warner Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17 (1997).

In contrast to the statements by Bard's employees, M3's own president and expert witnesses conceded infringement of Bard's '056 patent. For example M3's

president testified that the structure of M3's original needle met every claim element in asserted Claims 9-12 and 21-23 of the '056 patent. A7270-73. Additionally, M3's patent expert admitted that the original needle infringed Claim 21 of the '056 patent. A8603-04. It was also not disputed that M3's current needle is identical to the original infringing needles and meet every element of Claim 21 of the '056 patent except that the current needle does not have "flange means for coupling for forward and rearward movement" as required by the claim. M3's president also testified that the current needle has the same function, works in the same way, and accomplishes the same result as the original infringing needle. A7278; A7293-94. Further, M3's technical expert testified that the original and current needles are interchangeable. Clearly, substantial and convincing evidence was presented at trial, much of it stemming from M3's own admissions, demonstrating that M3's original and current needles infringe at least Claim 21 of Bard's '056 patent.

C. The Federal Circuit's Decision Properly Applied The *PRE* Standard On Sham Litigation

The Federal Circuit analyzed the sham litigation question in accordance with the standard set forth by the Court in *PRE* (54a):

> The Supreme Court in *Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc. ("PRE")* established the two-part criteria of "sham litigation": (1) the lawsuit must be objectively meritless such that "no reasonable litigant could expect success on the merits" and (2) it must be found that "the baseless lawsuit conceals 'an

> attempt to interfere *directly* with the business relationships of a competitor.'" *508 U.S. 49, 60, 26 USPQ2d 1641, 1646 (1993)* (emphasis in original) (quoting *Eastern R.R. President's Conf. v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 144 (1961)).

The Federal Circuit further relied upon *PRE* for the proposition that lack of success by a patentee in bringing suit does not, by itself, demonstrate that the patentee had engaged in sham litigation. 55a. The Federal Circuit observed that the only evidence presented by M3 at trial (*i.e.*, the opinion of a Bard engineer and other Bard employees) "does not constitute substantial evidence that this litigation was objectively meritless and brought in bad faith." 55a-56a. For example, the Federal Circuit noted that the Bard engineer testified that he did not know whether the individuals who thought that M3's current needles did not infringe Bard's '056 patent had ever read the patent, or whether they were familiar with the concept of infringement under the doctrine of equivalents. 55a-56a.

PRE requires an antitrust plaintiff first prove that the defendant's lawsuit was "objectively baseless" (*i.e.*, no reasonable *litigant* could expect success on the merits). *PRE*, 508 U.S. at 60; *see supra*, pp. 2-3. Thus, the *PRE* standard focuses on the "challenged lawsuit's *legal* viability." *Id.* at 61 (emphasis in original). The question of patent infringement involves a comparison of the properly construed patent claim to the accused device. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (*in banc*), *aff'd*, 517 U.S. 370 (1996). A determination of patent infringement must also include an assessment of whether the accused device infringes the asserted patent under the doctrine of equivalents. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 25-

28 (1998).

The only evidence presented by M3 on the sham litigation issue was the testimony of the Bard employees, which was based neither upon a reading of the '056 patent, nor upon an assessment of infringement under the doctrine of equivalents. 55a-56a. Under the Court's holding in *PRE*, these statements could not constitute evidence as to the *legal* viability of Bard's lawsuit. *See PRE*, 508 U.S. at 61. Thus, the Federal Circuit was correct in concluding that M3 failed to present sufficient evidence to meet *PRE's* "objectively baseless" requirement for sham litigation.

D. The Ninth Circuit's *Handgards* Decisions Have Been Effectively Overruled By *PRE*

The Ninth Circuit addressed the issue of antitrust liability resulting from commencement of a patent infringement action in "bad faith" in two related decisions. In *Handgards, Inc. v. Ethicon, Inc.*, 601 F.2d 986 (9th Cir. 1979), *cert. denied*, 444 U.S. 1025 (1980) ("*Handgards I*"), the Ninth Circuit reversed a jury verdict finding antitrust liability, and held that because there is a presumption of good faith on the part of litigants, a finding of bad faith must be based upon clear and convincing evidence rather than a mere preponderance of the evidence. *Handgards I*, 601 F.2d at 996.

In *Handgards, Inc. v. Ethicon Inc.*, 743 F.2d 1282 (9th Cir. 1984), *cert. denied*, 469 U.S. 1190 (1985) ("*Handgard II*"), the Ninth Circuit affirmed the jury verdicts of the district court that had been returned after remand of *Handgards I*, finding sufficient evidence of bad faith had been presented to meet the clear and convincing standard. *Handgards II*, 743 F.2d at 1292-93. The Court

in *Handgards II*, 743 F.2d at 1294-95, found that its standard for clear and convincing evidence of bad faith was consistent with the standard for "sham" litigation set forth by the Court in *California Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508 (1972):

> We believe that *Handgards I* established a standard that embodies both the *Noerr-Pennington* immunity and the sham exception. There we held that "the jury should be instructed that a patentee's infringement suit is presumptively in good faith and that this presumption can be rebutted only by clear and convincing evidence [of bad faith]." 601 F.2d at 996. The good faith presumption affords the equivalent of the *Noerr-Pennington* immunity while the requirement of bad faith litigation easily affords the equivalent of the sham exception. . . . Thus, to require a jury instruction as to *Noerr-Pennington* immunity and the sham exception would be duplicative. (footnote and citation omitted).

The "bad faith" which was referred to in both *Handgards I* and *Handgards II* was clearly a subjective standard. *See Handgards II*, 743 F.2d at 1289 ("All that is required for finding of the bad faith in the context of an infringement suit is that the patent holder, Ethicon, *knew* that its patent was invalid.") (emphasis added); *Handgards I*, 601 F.2d at 993 ("'Bad faith', however, is a subjective state of mind . . . ."). Since the Court in *PRE*, explicitly excluded a purely subjective standard for "sham" litigation, the *Handgards* cases, to the extent that they require *only* a showing of subjective bad faith, are not consistent with the *Noerr-Pennington* immunity, and have

been overruled by *PRE*[1]. *PRE*, 508 U.S. at 60.

Notably, the Ninth Circuit has neither relied upon the *Handgards* cases, nor applied a purely subjective test to "sham" litigation cases. Rather, the Ninth Circuit has consistently applied an objective test. *See, e.g., Columbia Picture Indus., Inc. v. Professional Real Estate Investors, Inc.*, 944 F.2d 1525, 1530-32 (9th Cir. 1991), *aff'd*, 508 U.S. 49 (1993). *See also Amarel v. Connell*, 102 F.3d 1494, 1518-19 (9th Cir. 1996).

E. M3's Conditional Cross-Petition For Writ Of Certiorari Should Be Denied

M3 suggests in its conditional cross-petition that a "newly-announced standard of proof" "in direct conflict" with *Handgards II* was created by the Federal Circuit which, as a "practical matter would make it impossible to prove a sham litigation claim." Pet. at 10. According to M3, the Federal Circuit created a "new rule" that an antitrust claim based upon "bad faith patent enforcement can be proved only by direct evidence that a representative of the patentee having specialized legal training . . . knew that the underlying infringement claim was baseless." Pet. at 10-11.[2] M3 misleadingly refers to the issue as "bad faith patent enforce-ment," attempting to use this term

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[1] Since the objective versus subjective standard was not disputed in either *Handgards* case, comments in either of those cases regarding the subjective standard are best considered merely dicta.

[2] M3 misleadingly frames the issue as "bad faith patent enforcement" by attempting to use this term interchangeably with "sham" litigation. *See, e.g.*, Pet. at 11. To the extent "bad faith patent enforcement" refers to an antitrust cause of action based solely on a defendant's subjective "bad faith" in commencing a patent lawsuit, such a cause of action is not recognized by *PRE*. *PRE*, 508 U.S. at 60.

interchangeably with "sham" litigation. *See, e.g.*, Pet. at 11. To the extent that "bad faith patent enforcement" refers to an antitrust cause of action based solely on a defendant's subjective "bad faith" in commencing a patent lawsuit, such cause of action does not exist. *PRE*, 508 U.S. at 60. M3 maintains that the Federal Circuit's decision conflicts with the holding of *Handgards II* that a plaintiff need not show knowledge of the lawsuit's baselessness by someone with legal training. Pet. at 12 (citing *Handgards II*, 743 F.2d at 1290 ("We refuse to establish a requirement that Handgards had to prove that the patent attorney knew the Gerard patent was invalid.")).

M3 next contends the Federal Circuit's decision would shift the burden of proof to an antitrust *plaintiff* to present an opinion of defendant's counsel to prove its *prima facie* case. According to M3, counsel's opinion is an affirmative defense to a charge of malicious prosecution which the *defendant* has the burden of proof. Pet. at 14. Thus, since a defendant can always assert attorney-client privilege to prevent an antitrust plaintiff from obtaining counsel's opinion, M3 erroneously concludes that the Federal Circuit's rule effectively prevents any plaintiff from proving its case of "bad faith patent enforcement." Pet. at 17.

M3's contentions, however, are without legal and factual support and are premised upon an inaccurate analysis of the Federal Circuit's decision.

II. REASONS FOR DENYING RESPONDENT'S CROSS-PETITION

A. There Is No Conflict Between The Federal Circuit And Ninth Circuit Regarding "Sham" Litigation

The Federal Circuit's decision was based on a proper application of the *PRE* "two-part definition" for "sham" litigation. 54a. Since the Ninth Circuit is obliged to, and does, follow the Court's precedent in *PRE*, there can be no conflict between the two Circuit Courts on this issue. *See Amarel v. Connell*, 102 F.3d 1494 (9th Cir. 1996).

The first part of the *PRE* standard requires a plaintiff to demonstrate that defendant's lawsuit was "objectively baseless" which requires an assessment of the "lawsuit's *legal* viability" from the perspective of a "reasonable litigant." *PRE*, 508 U.S. at 60-61. It is not disputed that the employee statements relied upon by M3 were made (a) without reading Bard's '056 patent, (b) without analyzing the asserted patent claims in light of the patent specification and prosecution history, and (c) without assessing the infringement issue under the doctrine of equivalents. 55a-56a. Since reading the asserted patent and considering the issue of the doctrine of equivalents are fundamental to a proper infringement analysis, the statements relied upon by M3 reveal nothing about the objective legal basis underlying Bard's lawsuit, nor do they shed any light on what a "reasonable litigant" would think about Bard's claims *See PRE* at 60-61. The Federal Circuit's decision finding these statements legally insufficient is entirely consistent with the *PRE* standard.

In contrast, the court in *Handgards II* was assessing a defendant's good faith belief under a purely *subjective* test. *Handgards II*, 743 F.2d at 1289. Under such an analysis, evidence of any employee's knowledge, with or without a legal basis for such knowledge, would be probative. *Id.* at 1290. However, the Court in *PRE* specifically rejected a purely subjective standard for sham litigation.

> In sum, fidelity to precedent compels us to reject a purely subjective definition of "sham." The sham exception so construed would undermine, if not vitiate, *Noerr*.

PRE, 508 U.S. at 60. Since the *Handgards* subjective standard has been overruled, it can no longer stand as a conflict with the Federal Circuit's holding.

B. The Federal Circuit's Decision Does Not Shift The Burden Of Proof In "Sham" Litigation Cases

The Federal Circuit, consistent with the *PRE* precedent, held that statements by Bard employees lacking a legal basis, alone, could not provide sufficient evidence to show that Bard's lawsuit was "objectively baseless" from the perspective of a "reasonable litigant." 55a-56a. *See PRE*, 508 U.S. at 60-61. Contrary to M3's contentions, the Federal Circuit did *not* hold that statements from employees with a legal basis constituted the *only* evidence which could be used to prove "sham" litigation. *See, e.g.*, Pet. at 10. The Federal Circuit did not address the sufficiency of any other type of evidence that could be used to show that a lawsuit was "objectively baseless" since M3 offered no such evidence. 55a-56a. The Federal Circuit's

decision also does not infer that direct evidence of the lack of technical merit of a lawsuit, such as a complete lack of evidence or legal basis for the defendant's claims, could not prove sufficient to meet the objectively baseless standard. *Cf. PRE*, 508 U.S. at 66-65 (lawsuit not objectively baseless where undisputed facts showed that defendant enjoyed a valid copyright and that, under the holdings of two other circuit courts, defendant might have prevailed on its legal theory). The Federal Circuit's decision clearly does not limit an antitrust plaintiff to reliance upon a defendant's opinions of legal counsel to support a sham litigation claim.

M3's attempt to draw an analogy between malicious prosecution and "sham" litigation misses the mark. Pet. at 14-15. Opinions of counsel that might form the basis for a defendant's affirmative defense in a malicious prosecution action are part of a completely different legal regime than the legally-grounded employee statements that might form the basis of a plaintiff's case-in-chief when alleging antitrust liability based on "sham" litigation. A plaintiff in a sham litigation case has the initial burden of proving that the defendant's lawsuit was *objectively* baseless. *PRE*, 508 U.S. at 60. The Federal Circuit held that M3 failed to meet its initial burden of proof. 56a. The Federal Circuit's decision, at most, merely *implies* that statements from defendant's employees, *which have a legal basis* and which state that defendant's lawsuit *did not have* merit, may be sufficient to meet that burden. *See* 54a-56a. The Federal Circuit's decision, however does not limit the evidence which can or cannot be sufficient to prove or rebut an inference of *subjective* intent. M3's claim that the Federal Circuit shifted an evidentiary burden, therefore, is completely without merit.

CONCLUSION

For these reasons, the conditional cross-petition for a writ of *certiorari* should be denied.

Respectfully submitted,

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